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IN THE
Supreme Court of the United States
October Term, 1992

RONNIE LEE AND MACKEY LEE,
INDIVIDUALLY AND AS PARENTS AND
NATURAL GUARDIANS OF MICHAEL LEE, A MINOR,
Petitioners,

v.

RICHARDSON-MERRELL, INC.,
Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether Fed. R. Civ. P. 56(e) and the Seventh Amendment permit federal courts to grant summary judgment on a contested factual issue, and take the issue from the jury, by weighing the relative credibility of the opinions of competing qualified experts.

2. Whether the lower federal courts possess inherent judicial power to impose nationwide uniformity on scientific issues common to diversity cases arising under the law of the 50 States, supposedly to prevent "inconsistent" verdicts on these scientific issues.

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OPINIONS BELOW

The opinion of the United States Court of Appeals for the Sixth Circuit, affirming the district court's grant of summary judgment for respondent, is unreported and is reprinted as Appendix A, at page **A1**. (References to the appendices bound with this petition are styled "**A**___"). The memorandum decision and order of the United States District Court for the Western District of Tennessee, from which appeal was taken, is reported at 772 F. Supp. 1027, and is reprinted as Appendix B, at page **A5**.

JURISDICTION

The decision of the court of appeals was announced on April 22, 1992. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS

Rule 56 of the Federal Rules of Civil Procedure provides, in relevant part, that:

> **(c)** . . . The judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. . . .
>
> **(e)** . . . When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of the adverse party's pleading, but the adverse party's response, by affidavits or otherwise provided by this rule, must set forth specific facts showing that there is a genuine issue for trial. If the adverse party does not so respond, summary judgment, if appropriate, shall be entered against the adverse party.

The Seventh Amendment to the United States Constitution provides that:

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by jury, shall otherwise be re-examined in any Court of the United States, than according to the rules of the common law.

STATEMENT OF THE CASE

1. This is a products liability case governed by Tennessee substantive law. The facts leading to the lawsuit are not disputed. Petitioners Ronnie and Mackey Lee are the parents of Michael Lee, who was born on March 27, 1974, with severe limb defects including shortness of his fingers, "webbing" between the fingers of his hands, and unnaturally small hands. The Lees filed suit against respondent Richardson-Merrell, Inc. ("Merrell") in the United States District Court for the Western District of Tennessee, alleging that Michael's limb defects had been caused by Bendectin, a prescription anti-nausea drug marketed by Merrell, which Michael's mother had taken during the limb-development phase of pregnancy. No identifiable risk factor other than ingestion of Bendectin was present. The collective testimony of seven concededly qualified experts was ultimately put forth at the summary judgment stage in support of causation. **(A2-A3, A6)**.

2. Merrell moved for summary judgment in the district court on the issue of causation. In its filing under Fed. R. Civ. P. 56(c) Merrell stated that it "denies that Bendectin contributed to the formation of these birth defects because Bendectin does not cause defects of any type, and therefore, could not have caused Michael Lee's deformities." Memorandum in Support of Summary Judgment, filed June 29, 1990, at 2. In support of its Rule 56(c) assertion that there is "no genuine issue of material fact" concerning whether Bendectin is a "teratogen" -- i.e., a substance capable of causing birth defects -- Merrell relied principally on the affidavit of Dr. Steven H. Lamm, a pediatrician. The Lees conceded that Dr. Lamm was qualified to state an opinion concerning the effect of Bendectin on birth defects.

Dr. Lamm's expert conclusion was: "[I]t is my opinion to a reasonable degree of medical and scientific certainty that maternal Bendectin ingestion is not associated with, and does not cause, limb reduction defects, generally or specifically." Aff. dated June 8, 1990, at ¶ 10(e). This ultimate statement of opinion about causation, standing alone, constituted admissible evidence, because Rules 704(a) and 705 of the Federal Rules of Evidence permit qualified experts to state their opinions on an ultimate issue of fact without disclosing the facts or data underlying the opinion. However, in several pages of his affidavit Dr. Lamm also outlined the general nature of his reasoning and the types of data he had relied on in forming his opinion. Dr. Lamm stated that he is an epidemiologist and that he had studied the available epidemiological data, published in medical and scientific articles, seeking to estimate the effect of Bendectin on mass human populations. Aff. at ¶¶ 5 and 6. Dr. Lamm looked at each published article individually and also analyzed the articles collectively "by a method known as pooling (or meta-analysis)," which he said is "an accepted practice in the field of epidemiology which allows for combining the results of numerous studies." Under neither method of analysis did Dr. Lamm perceive a causal link between Bendectin and birth defects. Aff. ¶¶ 10(b) and 10(c).

Although Dr. Lamm described generally the collection of articles he had considered, and although Merrell's lawyers provided a summary of each article and eventually attached copies of the articles to Merrell's summary judgment reply brief, *none* of these articles or other types of data relied on by Merrell's experts were entered into evidence as proof of non-causation. Rather, they were out-of-record hearsay sources to which Dr. Lamm freely and informally referred, as permitted by Rule 703 of the Federal Rules of Evidence. Rule 703, which is "[s]ometimes referred to as an 'expert testimony exception to the hearsay rule,' . . . broadens the acceptable bases for expert testimony by allowing an expert to base an opinion on hearsay and other evidence not admissible in court." *Ambrosini v. Labarraque*, Nos. 90-7146 & 90-7148 (D.C. Cir. June 12, 1992) (reprinted as Appendix D, at **A40**, **A43**) (quoting *United States*

v. Unruh, 855 F.2d 1363, 1376 (9th Cir. 1987), *cert. denied*, 488 U.S. 974 (1988)).[1] This hearsay data, of course, "does not come in as substantive evidence," and only "is admitted at trial for the limited and independent purpose of enabling the jury to scrutinize the expert's reasoning." *United States v. Wright*, 783 F.2d 1091, 1100 (D.C. Cir. 1986).

Merrell also produced the affidavit of Sherman Elias, M.D., whom the Lees also conceded was qualified to state an opinion concerning the effect of Bendectin on birth defects. Dr. Elias stated that, in his opinion, "there is no evidence of an increased frequency of birth defects in those children whose mothers took Bendectin during pregnancy as compared to those children whose mothers did not take Bendectin during pregnancy." Aff. dated June 25, 1990, at ¶ 10. Dr. Elias stated that he based this conclusion partly on his review of epidemiological articles concerning Bendectin, and partly on his past practice in obstetrics and gynecology in which he had delivered about 600 infants, some of whose mothers had been prescribed Bendectin. Aff. at ¶ 5-9.

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[1] *See also Rogers v. Raymark Industries, Inc.*, 922 F.2d 1426, 1429-30 (9th Cir. 1991) ("an expert opinion may be based on any type of evidence commonly used in the field"); *United States v. Lundy*, 809 F.2d 392, 395-96 (7th Cir. 1987) ("hearsay and third-party observations that are of a type normally relied upon by an expert in the field are properly utilized by such an expert in developing an expert opinion"); *Clinchfield Railroad Co. v. Lynch*, 784 F.2d 545, 553-544 (4th Cir. 1986) (after Rule 703 showing that facts or data are "regularly relied upon" by experts in the field, questions going to weight are to be "'attacked by cross examination and refutation'"); *United States v. Tranowski*, 659 F.2d 750, 755 n.10 (7th Cir. 1981) ("Rule 703 permits a court to admit an expert opinion based on hearsay, if reliance on such factual bases is the normal practice of experts in the field in reaching their conclusions"); *Mannino v. International Manufacturing Co.*, 650 F.2d 846, 851 (6th Cir. 1981) ("[t]he purpose of Rule 703 is to make available to the expert all of the kinds of things that an expert would normally rely upon in forming an opinion, without requiring that these be admissible in evidence," and through it "the law is catching up with the realities of professional life"); *Kingsley Associates, Inc. v. Del-Met, Inc.*, 918 F.2d 1277, 1286-87 (6th Cir. 1990) (reaffirming *Mannino*).

As required by Fed. R. Civ. P. 56(e), the Lees opposed summary judgment with affidavits "set[ting] forth specific facts showing that there is a genuine issue for trial." The expert conclusions of a total of seven expert witnesses, skilled in several relevant scientific and medical disciplines, were presented. (See generally **A9-A10**). Merrell readily conceded that each of the seven experts was qualified to state an opinion concerning the effect of Bendectin on birth defects. These experts presented conclusions that were based on one or more of the four standard sources of information that scientists routinely consult in assessing whether particular substances are teratogens: (1) *in vitro* animal tests on animal cells, (2) *in vivo* animal tests on live animals, (3) analysis of chemical structure, and (4) analysis of data contained in the same published epidemiological studies considered by Merrell's experts. The affidavits of the Lees' experts provided affirmative proof that Bendectin is a teratogen and also criticized as simplistic and misleading the reliance of Merrell's experts *solely* on medical data drawn from the fourth category, epidemiological data.[2] Under Fed. R. Evid. 704(a)

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[2] For example:

- Univ. of Texas epidemiology and biostatistics professor Jay H. Glasser, Ph.D, previously appointed by the federal bankruptcy court to perform epidemiological analysis in the Dalkon Shield cases, analyzed all published epidemiological data -- considered both individually and considered collectively through "pooling" or "meta-analysis," as did Dr. Lamm -- and concluded that "Bendectin is within a reasonable degree of epidemiological certainty associated with congenital disorders, including limb defects." Aff. dated Sept. 27, 1989, at ¶¶ 5, 9-11.
- Shanna Swan, Ph.D, Chief of California's Reproductive and Epidemiological Program and previously consultant to the World Health Organization, FDA and NIH, specifically rebutted the analysis of Dr. Lamm, stating that "one cannot draw a conclusion from [available epidemiological] studies that Bendectin does not cause limb reduction defects"; based on her own analysis she concluded from the studies, "within a reasonable degree of certainty, based on all of the available data, that Bendectin is associated with birth defects, including limb defects." Aff. dated Sept. 27, 1989, at ¶¶ 10 and 13.
- UCLA biology professor Frederick Crescitelli, Ph.D, stated his opinion "within a reasonable degree of scientific certainty, that . . . Bendectin . . . is a teratogen," and stated that "it is scientifically improper to rely solely upon epidemiological studies to determine whether or not a

and 705 these ultimate conclusions, like those of Merrell's experts, standing alone constituted admissible evidence on the issue of causation. Although the Lees' experts referred to numerous sources of data in support of their opinions, including specific scientific studies and published articles, like the sources relied on by Merrell's experts these sources were not themselves admitted as evidence but simply elaborated the types of hearsay sources that would be discussed before the trier of fact.

3. On this record the district court granted summary judgment. In analysis not relevant to the issues presented by the instant petition, the district court concluded that all of the Lees' expert opinion testimony was inadmissible in light of the supposedly "overwhelming contrary epidemiological data" to which Merrell's experts alluded in their affidavits. (**A11**). In so ruling, the district court elected to follow several other courts that had found, on different records involving different evidence,

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drug is a teratogen," and that "much better scientific data includes pharmacology data, animal studies, and *in vitro* studies." Aff. dated Sept. 26, 1989, at ¶¶ 2, 7-8.

• Likewise, medical professor Stuart A. Newman, Ph.D, a specialist in limb development defects for 17 years, NIH consultant and peer reviewer for leading journals and the National Science Foundation, stated that "it is my opinion within a reasonable degree of scientific certainty that . . . Bendectin . . . is a teratogen"; stated that this conclusion was based on "laboratory science, which is considered a 'hard science'" in its verifiability and precision, and contrasted these methods with "epidemiology which is known as a 'soft science' because of the extreme numbers of variables that are involved and the inability to perform well-controlled experiments"; and further stated that "[p]rofessional scientists . . . would not rely solely upon epidemiological data to draw conclusions about the ability of a chemical, e.g., drug, to [a]ffect the cells in the developing human fetus." Aff. dated Mar. 27, 1990, at ¶¶ 2 and 9.

• EPA Senior Science Advisor Adrian Gross, V.D.M., formerly Chief of Pathology for the FDA, detailed his exhaustive knowledge of relevant animal studies and gave his "strongly-held view that the animal studies do indicate clearly and unambiguously that Bendectin is a developmental toxicant," i.e., it "has the capacity to interfere with the normal development of cells in the human being and thus is a teratogen in the human being, at the normal therapeutic dose." Aff. dated Sept. 26, 1989, at ¶¶ 9 and 13.

particular expert opinion testimony concerning Bendectin to be inadmissible. (**A13-A16**). The district court's exclusion of all of the Lees' evidence concerning causation necessarily led it to grant summary judgment in favor of Merrell. (**A17**).

4. On review, the United States Court of Appeals for the Sixth Circuit affirmed the grant of summary judgment in an opinion that assumed the admissibility of all of the Lees' expert testimony, but concluded that the content of that testimony could not establish causation. (**A4**). Given this approach, the court of appeals evaluated a record containing the admissible opinions of two Merrell experts who relied on a single source of hearsay information (epidemiological data) to conclude that Bendectin cannot cause birth defects, placed against the admissible opinions of seven Lee experts relying on four sources of hearsay information to conclude the opposite. Despite these conflicting opinions by qualified experts on the central issue in the case, the court of appeals did not end its inquiry into sufficiency. It went further to consider the weight of the Lees' "scientific evidence, taken as a whole," and held that this evidence "fails to create a genuine issue of material fact" under Rule 56(e). (**A4**).

In weighing the credibility of the ultimate opinions advanced by the Lees' experts, the court of appeals stated that there was no need to engage in a *de novo* analysis of the record in the case to assess those opinions, either standing alone or in comparison to the opinions of Merrell's experts. Rather, the Sixth Circuit panel in the instant case simply adopted the scientific conclusion pronounced by a separate Sixth Circuit panel that had reviewed a grant of summary judgment in another Bendectin case, in which the Lees were not involved and which presented a different plaintiff, different underlying facts, and the substantive law of a different state. As the Sixth Circuit panel below held:

> We conclude that a finding of a causal relationship between Bendectin use and Michael Lee's birth defects based upon this evidence would be conjectural at best in light of this court's recent opinion in *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, No. 90-5690 (6th Cir. March 11, 1992). In

> *Turpin*, another panel of this court reviewed the scientific data on Bendectin in great detail and concluded that the evidence presented by the plaintiffs' experts fell short of showing that 'Bendectin more probably than not causes limb defects in children born to mothers who ingested the drug at prescribed doses during pregnancy.' Slip op. at 24.

(**A3**). In the view of the panel below, "[t]he evidence presented by the Lees in the instant case is identical in all material respects to the evidence relied on by the plaintiffs" in *Turpin*, so that the panel felt justified in viewing the matter as settled on the record that existed in *Turpin*. The panel held: "For the reasons stated in *Turpin*, we view this testimony as unable to bridge 'the analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue of human birth defects . . . .' Slip op. at 24." (**A4**).

In adopting the factual conclusions reached by the *Turpin* panel based on the record in that case, the appellate panel below made no effort to conform its action to Fed. R. Evid. 201(a), which permits courts to rely on a "judicially noticed fact" only where it is one "not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Nor did the panel afford the Lees any "opportunity to be heard as to the propriety of taking judicial notice and the tenor of the matter noticed." Fed. R. Evid. 201(e).

5. The Sixth Circuit's *Turpin* decision, reprinted as Appendix C, at **A18** (see also 959 F.2d 1349 (6th Cir. 1992)), considered and answered two general legal issues of importance to many cases in the federal court system, on which several circuits are in substantial conflict. A petition for certiorari seeking review of the *Turpin* decision is currently pending before this Court. See Petition for Certiorari, *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, No. 91-1987 (filed June 9, 1992). Through its complete incorporation of the *Turpin* analysis, the panel decision below in the instant case presents these same

issues, and this petition for certiorari (with Questions Presented identical to *Turpin*, but with somewhat different arguments) has been filed accordingly. If this Court grants review of the *Turpin* petition, it should also grant review of the instant petition and either consolidate the two cases for oral argument or hold one pending disposition on the merits of the other. Even if this Court denies review of the *Turpin* petition, it should separately consider the merits of the instant petition because the decision of the panel below to accord conclusive weight to out-of-record factual judgments from another case raises important and troubling issues concerning judicial notice and due process that are not present in the *Turpin* case. *See* pp. 23-24, *infra*.

As to the two key issues contained in the holding of the *Turpin* panel and thus in the decision below:

First, in *Turpin* the court of appeals asked "whether a court should judge for itself the validity of the reasoning process by which various competing qualified experts have reached their conclusions or should instead leave that question for the jury." (**A18**). In other words, upon the presentation of qualified, admissible expert opinion testimony establishing a conflict over factual issues under Fed. R. Civ. P. 56, the court of appeals asked whether a court may proceed to judge the credibility of the opinions itself rather than leaving that function to the jury. It held that: "[A]lthough judges should respect scientific opinion and recognize their own limited scientific knowledge, nevertheless courts have a duty to inspect the reasoning of qualified scientific experts to determine whether a case should go to the jury." (**A18-A19**).

Second, the court of appeals considered the relevance of a pattern of inconsistent jury verdicts nationwide to the issue of how closely a court should scrutinize, on summary judgment, the credibility of competing expert opinions. The court left no doubt as to its concern about this phenomenon:

> For a judicial system founded on the premise that justice and consistency are related ideas, the inconsistent results reached by courts and juries nationwide on the question of causation in Bendectin birth defect cases are of serious concern.

(**A18**). The court of appeals explained that because of similar evidence, even though different plaintiffs and injuries are at issue in each case, Bendectin cases nationwide "are variations on a theme, somewhat like an orchestra which travels to different music halls, substituting musicians from time to time but playing essentially the same repertoire." (**A20**). Surveying recent caselaw, the court found massive inconsistency in the federal courts and, to a lesser extent, in the state courts: some juries found particular injuries caused by Bendectin while others refused to so find; some trial courts ruled expert opinion admissible and sufficient while other courts ruled to the contrary on one or both issues; and appellate courts were divided both ways. (**A20-A23**).

As the court of appeals analyzed the situation, this inconsistency was a problem originating from insufficient judicial will to confront the need for a solution:

> The fundamental reasons for the inconsistency of the legal system in handling Bendectin claims appear to be first, the difficulty of scientists and hence of judges, lawyers and jurors in knowing what reasonable inferences of causation to draw from animal experiments and epidemiological studies; and second, the uncertainty of judges about how far they should enter the scientific thicket of conflicting inferences in order to determine whether the basis of a scientific opinion concerning causation is sufficiently plausible to allow a jury to ground a verdict on it.

(**A23**).

Surveying the administrative law context in search of the appropriate solution, the court of appeals concluded that the danger that different juries might reach inconsistent results on common issues of scientific fact requires judges to "apply a 'hard look' doctrine . . . in scientific cases based primarily on expert testimony," one that ensures "close judicial analysis of such technical and specialized matter." (**A23**). The court of appeals justified this choice "not only because of the likelihood of juror misunderstanding, but also because expert witnesses are not necessarily always unbiased scientists," but instead "are paid by

one side for their testimony," thus producing the "potential for exaggeration and fraud" that only a court could discern, through "close inspection and careful consideration of the record." (**A23-A24**). Only through this means, the court of appeals concluded, could it guard against what it saw as "a 'combination of danger signals' requiring enhanced 'judicial vigilance to enforce the Rule of Law.'" (**A24** (citation omitted)).

Applying this dual approach -- requiring judicial scrutiny of the weight of competing expert opinions on a Rule 56 summary judgment analysis, coupled with an especially intense "hard look" review to prevent undue inconsistency in jury verdicts -- the court of appeals then rendered a decision on the facts of the *Turpin* case.

On the one hand, after an exhaustive, detailed review of the epidemiological studies relied on by Merrell's three experts in that case (see **A25-A31**), the court of appeals agreed with criticisms of these studies put forth by the Turpins' experts. (See **A31-A33**). Although these studies "constitute[d] evidence on which a jury might ground a defendant's verdict," they were "by no means conclusive." Merrell's experts had "overstate[d] the persuasive power of these statistical studies." (**A33**). The current science of epidemiology, the court ruled, could not eliminate "significant scientific uncertainty" about the value of the epidemiological studies that lay at the foundation of Merrell's defense. (**A33**).

Rather than concluding that Merrell had failed in its strategy of attempting to produce under Rule 56(c) supposedly "overwhelming" epidemiological evidence in hopes of somehow outweighing the Turpins' Rule 56(e) production of expert testimony, the court of appeals moved on to an equally exhaustive analysis of the Turpins' expert affidavits. Specifically, the court focused on animal studies -- one of the chief sources relied on by the Turpins' experts. (See **A33-A37**). Here the court found what it regarded as "[t]he weakness of the plaintiffs' case." (**A36**). The problem was simple: "This weakness arises from the fact that different species of animals react differently to the same stimuli for reasons not entirely

understood," so that it might not be reasonable in a particular case for "a reasonable jury to find that it is more probable than not that the substance causes a similar harm to humans." (**A36-A37**). The Turpins' experts (like Merrell's experts) had relied in part on animal studies in forming their opinions on causation, but the court of appeals could not find that the resulting conclusion in favor of causation was "anything more than a personal belief or opinion," although it did not explain what it meant by this statement. (**A38**). In the concise opinion testimony put forth by the Turpins only to *identify* a "genuine issue of material fact" on summary judgment rather than to *adjudicate* that fact at trial, the court did not discern an "understandable scientific basis." (**A38**). The expert testimony, the court found, went "far beyond the known facts" and was "overstate[d]." While recognizing that "[a]nimal studies often comprise the backbone of evidence indicating biological hazards, and their legal value has been recognized by federal courts and agencies," (**A38**), on a record of this nature the court of appeals insisted that the "analytical gap" was simply "too wide," and upheld the grant of summary judgment, which it felt was necessary to ensure consistent jury verdicts. (**A39**).

REASONS FOR GRANTING THE WRIT

1. This Court Should Resolve the Circuit Conflict Over Whether Federal Courts May Grant Summary Judgment On Contested Factual Issues by Weighing the Relative Credibility of the Opinions of Competing Qualified Experts

The Sixth Circuit in *Turpin* opined that on a summary judgment ruling "a court should judge for itself the validity of the reasoning process by which various competing qualified experts have reached their conclusions," rather than "leav[ing] that question for the jury," (**A18**). The Sixth Circuit squarely applied that approach in upholding summary judgment in this case. (**A3-A4**). This case thus fuels the continuing conflict in the circuits over whether such close judicial scrutiny of expert opinion testimony is permissible under Fed. R. Civ. P. 56(e).

The conflict is the product of tension between two provisions: Rule 56(e) promulgated by this Court in 1963, which requires summary judgment affidavits to "set forth specific facts," and Fed. R. Evid. 705, enacted by Congress in 1975, which states that an expert may render his or her opinion "and give his reasons therefore *without* prior disclosure of the underlying facts or data" (emphasis added). This issue is important to all types of expert opinion testimony, not just to testimony concerning scientific issues, and fully warrants this Court's plenary review.

The second-to-last sentence of Fed. R. Civ. P. 56(e) requires that when a party answering a summary judgment motion submits affidavits or other materials, these materials "must set forth specific facts showing that there is a genuine issue for trial." This requirement was added through the 1963 amendment of Rule 56(e), "to disapprove a line of cases allowing a party opposing summary judgment to resist a properly made motion by reference only to its pleadings." *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). Under it, the nonmoving party may oppose with "any of the kinds of evidentiary materials listed in Rule 56(c), except the mere pleadings themselves." *Id.* at 324.

Despite its original limited aim, during the past decade this new requirement of Rule 56(e) has been employed by several circuits as an all-purpose tool for judging the credibility of expert opinions on particular factual issues. Even though these opinions are rendered by qualified experts in admissible form and thus may be believed by a jury, several circuits have assumed unbridled discretion under Rule 56(e) to grant summary judgment where they believe that the *reasoning* and *information* cited in support of the expert's ultimate opinion does not include enough "specific facts."

The earliest circuit to adopt this approach unambiguously was the Ninth Circuit. In *United States v. Various Slot Machines on Guam*, 658 F.2d 697 (9th Cir. 1981), the court noted that Rules 704 and 705 of the Federal Rules of Evidence explicitly permit an expert to present an opinion that "embraces an ultimate issue to be decided," and to do so "without prior disclosure of the underlying facts or data, unless the court requires otherwise."

Id. at 700. "[I]t can be argued," the Ninth Circuit explained, "that an expert's conclusion or opinion meets the requirement of Rule 56(e) that the party opposing the motion 'must set forth specific facts showing that there is a genuine issue for trial.'" *Ibid.* But the Ninth Circuit rejected this straightforward reading of the relevant language, stating that it had "difficulty with the notion that to state an opinion is to set forth specific facts," and it held that "in the context of a motion for summary judgment, an expert must back up his opinion with specific facts." *Ibid.*

The Ninth Circuit was followed by the Eleventh Circuit in *Evers v. General Motors Corp.*, 770 F.2d 984 (11th Cir. 1985). In *Evers*, a highly qualified automobile engineer stated by affidavit that he was thoroughly familiar with various categories of facts concerning a particular car accident, and he gave an ultimate opinion that provision of an airbag in the car would have minimized injuries to the occupants. With much of the same tone found in the Sixth Circuit's opinion in *Turpin* and in the opinion below, the Eleventh Circuit granted summary judgment to the defendant, complaining that the affidavit, "though it purports to be based upon a review of the evidence, fails to provide *specific* facts to back up its conclusory allegations" -- that is, it did not explain in detail *why* and *how* the expert had reached his conclusion. *Id.* at 986-87 (emphasis added). The court specifically rejected the claim that enactment of Rule 705 "alter[ed] the requirement of [Rule] 56(e) that an affidavit must set forth specific facts in order to have any probative value." *Ibid.*

The Seventh Circuit has also recently used Rule 56(e) to abort the trial of factual issues even where admissible expert opinions have been offered, if the court finds these opinions lacking in specifics and therefore in perceived utility. For example, in *Mid-State Fertilizer Co. v. Exchange National Bank*, 877 F.2d 1333 (7th Cir. 1989), a highly qualified banking expert stated several ultimate opinions on a banking arrangement; his opinions were in admissible form and described generally the information on which they were based. The Seventh Circuit upheld the district court's finding that the affidavit was

insufficient, stating that, although "Rule 705 of the Federal Rules of Evidence allows experts to present naked opinions," "[a]dmissibility does not imply utility"; the court complained that the expert "presented nothing but conclusions -- no facts, no hint of an inferential process, no discussion of hypotheses considered and rejected." *Id.* at 1339. The court observed that "[a]n expert who supplies nothing but a bottom line supplies nothing of value to the judicial process." *Ibid.* The court bluntly warned that "[j]udges should not be buffaloed by unreasoned expert opinions" and that "'[t]he importance of safeguarding the integrity of the [judicial] process requires the trial [or appellate] judge, when he believes that an expert's testimony has fallen below professional standards, to say so, as many judges have done.'" *Id.* at 1340 (citation omitted). *See also Kenosha Liquor Co. v. Heublein, Inc.*, 895 F.2d 418, 420 (7th Cir. 1990) (holding: "Expert opinions are worthless without data and reasons. Kenosha Liquor has a worthless opinion, and Heublein is entitled to judgment.").

The reasoning of the contrary line of cases is most succinctly summed up by a sentence in the recent Tenth Circuit opinion in *Quinton v. Farmland Industries, Inc.*, 928 F.2d 335 (10th Cir. 1991). Stating that a challenge to sufficiency of evidence on a factual issue must fail if there is admissible expert opinion testimony on the issue, the court stated: "It is a truism that 'an expert's opinion or interpretation of evidence is itself evidence.'" *Id.* at 338 (quoting *Rodriguez v. Olin Corp.*, 780 F.2d 491, 496 (5th Cir. 1986)). In other words, the opinion, if believed by the jury, establishes a fact and thereby itself can suffice to meet the requirement of Rule 56(e) that "specific facts" be set forth. As several circuits have recognized, this conclusion logically flows from the language of the expert testimony rules of the Federal Rules of Evidence, Congress's purpose in enacting them, and the constraint of the Seventh Amendment.

The opinions of the D.C. Circuit are especially clear. The most important principle is that under the expert testimony rules as structured by Congress, when an expert *does* elect in an affidavit to provide significant detail about the data and reasoning

forming the basis of his or her opinion -- as did the Lees' experts in this case -- this detail is *not* something that thereby goes into evidence, becomes accessible to weighing and scrutiny by the court, and thus might warrant a grant of summary judgment for insufficiency. Instead, when an expert provides such detail he or she does so by virtue of Rule 703, which overrides for experts the "prohibition against hearsay evidence" and "permits an expert witness to base his opinion on facts or data which would not be admissible as competent evidence so long as the facts or data are of a type reasonably relied on by experts in the particular field." *United States v. Wright*, 783 F.2d 1091, 1100 (D.C. Cir. 1986). *See also* pp. 3-4 & note 1, *supra*. The only purpose of such detail is to bolster the *credibility* of the expert. "Read together, Rules 703 and 705 reveal that the data underlying an expert's opinion which is elicited on cross-examination does not come in as substantive evidence," and only "is admitted for the limited and independent purpose of enabling the jury to scrutinize the expert's reasoning." *Ibid*. Under the structure established by Congress, a court has no business looking to this underlying detail on its own in order to find the expert not credible.

The Fourth Circuit echoed this construction of Rules 703 and 705 in its recent decision in *United States v. A & S Council Oil Co.*, 947 F.2d 1128 (4th Cir. 1991). The court recognized that under the expert testimony rules an expert witness is permitted to introduce into evidence general opinions concerning a given factual issue, and that such generality without a check of some sort could be dangerous. But Congress structured the Rules to ensure that a vigorous adversarial process would be available to cure potential abuses:

> Full examination of the underpinnings of an expert's opinion is permitted because the expert, like all witnesses, puts his credibility in issue by taking the stand.
>
> * * *
>
> . . . Rule 703 creates a shield by which a party may enjoy the benefit of inadmissible evidence by wrapping it in an expert's opinion; Rule 705 is the cross-examiner's sword, and, within very broad limits, he may wield it as he likes.

Id. at 1135. *See also Smith v. Ford Motor Co.*, 626 F.2d 784, 793 (10th Cir. 1980), *cert. denied*, 450 U.S. 918 (1981) ("[t]he combined effect of these new rules [Rules 703 and 705] is to 'place the full burden of exploration of the facts and assumptions underlying the testimony of an expert witness squarely on the shoulders of opposing counsel's cross-examination'") (citations omitted); *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 956 (3d Cir. 1990) (the Rules "embody a strong and undeniable preference for admitting any evidence having some potential for assisting the trier of fact and for dealing with the risk of error through the adversary process") (citing *Barefoot v. Estelle*, 463 U.S. 880, 899, 901 n.7 (1983)).

As the D.C. Circuit held in a decision involving causation issues in a landmark toxic tort case, when qualified experts testify to different conclusions about causation relying on similar sources of data and "differ[] solely on the conclusions they [draw] from the test results and other information," this is a "classic battle of the experts . . . in which the jury must decide the victor." *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1535 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984) (citation omitted). As to the claim that the defendant's claim of non-causation was so strong that the jury should not be allowed to disbelieve it, the *Ferebee* court remarked that "[t]he short answer to [defendant's causation] argument is that two expert witnesses refuted it and that the jury was entitled to believe those experts." *Ibid.* Recently, in *Ambrosini v. Labarraque*, Nos. 90-7146 & 90-7148 (D.C. Cir. June 12, 1992) (reprinted as Appendix D, at **A40**), the D.C. Circuit reaffirmed its *Ferebee* decision. (**A49**). Moreover, the D.C. Circuit made clear that the Rule 56(e) requirement that an expert's affidavit "must set forth specific facts showing that there is a genuine issue for trial" does *not* license federal courts to hold that if experts "do not set forth the 'specific facts' or reasoning behind their opinions, they are insufficient." (**A51**). Overturning a district court's grant of summary judgment on causation in a toxic tort case, the D.C. Circuit held that the key expert had "stated a specific fact" -- the fact of causation -- when he concluded without detail that the product at issue "caused Teresa Ambrosini's birth defects." (**A51**).

The D.C. Circuit's *Ferebee* and *Ambrosini* holdings are consistent with this Court's approach to credibility issues generally and to expert witness credibility in particular. This Court has explained that, under Rule 56(e), a "dispute about a material fact is 'genuine' . . . if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). As this Court observed in *Anderson*, "it is clear enough from . . . recent cases that at the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Id.* at 249. Most fundamentally, this Court has emphasized, the role of the jury may not be denigrated through use of "trial on affidavits," because "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions." *Id.* at 255. It is the very "'purpose of the jury . . . to sort out the true testimony from the false, the important matters from the unimportant matters, and, when called upon to do so, to give greater credence to one party's expert witnesses than another's. Such matters occur routinely in the American judicial system, both civil and criminal.'" *Barefoot v. Estelle*, 463 U.S. 880, 902 (1983) (citation omitted).

The distortion of Rule 56(e) by several circuits to authorize judges to perform these forbidden functions and judge expert witness credibility on their own is in plain conflict with the Seventh Amendment, because it has no conceivable analogue to any procedural mechanism that existed in 1791. *See Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 336-37 (1979). The Seventh Amendment's history makes clear that its central mission is to prevent just such a takeover of jury functions and thus to check the power of autocratic, life-tenured federal judges by entrusting factual disputes to people other than the sovereign's judges, however inefficient this can at times be. *See id.* at 337-56 (Rehnquist, J., dissenting); *see also Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 83 (1989) (White, J., dissenting) ("'The function of the civil jury is to diffuse the otherwise autocratic power and authority of the judge.'") (citation omitted). The

square holding of the court below that a court may "judge for itself the validity of the reasoning process by which various competing qualified experts have reached their conclusions" rather than "leav[ing] that question for the jury" (**A18**) is indefensible. The plenary attention of this Court over the Rule 56(e) circuit conflict and over such casual disrespect for the Seventh Amendment is necessary.

2. This Court Should Decide Whether Federal Courts Possess Inherent Judicial Power to Battle "Inconsistent" Jury Verdicts by Imposing Nationwide Uniformity on Scientific Issues Common to Diversity Cases Arising Under The Law of the Fifty States

In its *Turpin* opinion the Sixth Circuit boldly created an *ad hoc* mechanism designed to solve the supposed problem of "inconsistent results reached by courts and juries nationwide on the question of causation in Bendectin birth defect cases." (**A18**). In the decision below, the Sixth Circuit carried out that mission by giving judicial notice and conclusive weight to off-the-record factual assessments made by other judges in the separate *Turpin* case. The course chosen by the Sixth Circuit demonstrates a lack of respect for fundamental limits on judicial power -- particularly the restraints imposed by basic due process, Fed. R. Evid. 201, and the *Erie* doctrine.

The instant case therefore presents this Court with an opportunity to speak with a united voice concerning the limits of inherent judicial power, a subject which engendered a 5-to-4 split in the recent case of *Chambers v. NASCO, Inc.*, 111 S. Ct. 2123 (1991). The majority in *Chambers* ruled that the scheme of statutes and rules provided by Congress to target bad-faith conduct had not "displace[d] the inherent power to impose sanctions" for such activity. *Id.* at 2134. Although on the facts of the case the majority did not perceive "that the District Court's reliance on the inherent power thwarted the purposes of the other sanctioning mechanisms," *id.* at 2136, the majority reaffirmed that "[b]ecause of their very potency, inherent powers

must be exercised with restraint and discretion," *id.* at 2132, and that "the exercise of the inherent power of lower federal courts can be limited by statute and rule, for '[t]hese courts were created by act of Congress.'" *Id.* at 2134 (citation omitted). The majority also reaffirmed that any exercise of inherent powers must not violate the twin aims of this Court's *Erie* jurisprudence, of discouraging forum-shopping and avoiding inequitable administration of the laws. *Id.* at 2137.

Justice Kennedy, in dissent, also emphasized that "[i]nherent powers are the exception, not the rule, and their assertion requires special justification in each case," and that the lower federal courts must not be permitted "to ignore express Rules and statutes on point." *Id.* at 2143 (Kennedy, J., joined by Rehnquist, C.J. and Souter, J., dissenting). Strongly focusing on the *Erie* point, Justice Kennedy expressed concern that permitting use of inherent powers to impose sanctions for prelitigation primary conduct "violates the fundamental tenet of federalism announced in *Erie* by regulating primary behavior that the Constitution leaves to the exclusive province of States," with the result that "[r]espondent's decision to bring this suit in federal rather than state court resulted in a significant expansion of the substantive scope of his remedy," a "result prohibited by *Erie* and the principles that flow from it." *Id.* at 2148-49. Justice Scalia also voiced serious concerns, arguing among other things that "Congress may prescribe the means by which the courts may protect the integrity of their proceedings," and that "[a] court must use the prescribed means unless for some reason they are inadequate." *Id.* at 2140-41 (Scalia, J., dissenting).

In setting out on its bold enterprise below, the Sixth Circuit paid no heed to any of these principles. Such disrespect provides common ground for the majority and dissenting Justices in *Chambers* and presents an important opportunity for this Court to underscore to the lower federal courts basic axioms regarding the limits of judicial power.

Perhaps the most illegitimate feature of the decision below lies in its strange assumption that different jury verdicts in cases involving different Bendectin plaintiffs is a "problem" in demand

of a judicial "solution" -- here a solution that applies the administrative law "hard look" doctrine to civil diversity cases out of a fear that juries cannot be trusted to perceive the "danger signals" that sometimes accompany expert testimony. (**A23-A24**).

In fact, this pattern of so-called "inconsistency" is simply an endemic feature of a case-by-case system of adjudication coupled with the use of a lay jury as a means of providing a needed check on the power of the life-tenured Judiciary. As Justice Kennedy observed in the far more visible and troublesome area of inconsistent punitive damage awards, the evolution of the jury system over the centuries in general demonstrates that "[o]ur legal tradition is one of progress from fiat to rationality," and "[e]lements of whim and caprice do not predominate" in a properly functioning jury system. *Pacific Mutual Life Ins. Co. v. Haslip*, 111 S. Ct. 1032, 1055 (1991) (Kennedy, J., concurring in the judgment). "Some inconsistency of jury results can be expected," of course, partly because "the jury is empaneled to act as a decisionmaker in a single case, not as a more permanent body. As a necessary consequence of their case-by-case existence, juries may tend to reach disparate outcomes based on the same instructions." *Ibid.* Indeed, in the area of *criminal* law -- even in the *same* case -- "[i]t has, of course, long been the rule that consistency in verdicts or judgments of conviction is not required." *Hamling v. United States*, 418 U.S. 87, 100 (1974). In fact, "'it is common experience that different juries may reach different results under any criminal statute. That is one of the consequences we accept under our jury system.'" *Ibid.* (citation omitted).

Although an argument might be made that the Sixth Circuit's "solution" to the problem of inconsistency is from some perspective more efficient or rational than the current system, that calculus is irrelevant. As Chief Justice Rehnquist stated some time ago, any such sentiment "cannot obscure or dilute [the] obligation to enforce the Seventh Amendment, which *was* included in the Bill of Rights in 1791," based on the view that civil jury trials are "an important bulwark against tyranny and

corruption," not on the view "that use of juries would lead to more efficient judicial administration." *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 338, 343 (1979) (Rehnquist, J., dissenting) (emphasis in original). In sum, "no amount of argument that [a new procedural] device provides for more efficiency or more accuracy or is fairer will save it if the degree of invasion of the jury's province is greater than allowed in 1791." *Id.* at 346.

Indeed, the preeminent role given the jury in our civil justice system reveals the fundamental consistency underlying what on the surface might appear to be a pattern of inconsistent verdicts in cases involving different plaintiffs but similar scientific evidence. "[T]he many ways in which lawyers are accustomed to talking about 'inconsistency' in the law do not really conflict with the widespread assumption that legal systems are consistent." Rogers and Molzon, *Some Lessons About the Law From Self-Referential Problems in Mathematics*, 90 Mich. L. Rev. 992, 1000 (1992). One can conclude that these "different results are but *consistent* applications of the higher rule (metarule)," *id.* at 1001 (emphasis added), that operates here. The core function of the jury is to check the discretion of Article III judges by evaluating the weight of evidence and the credibility of witnesses. *See* page 18, *supra*. Obviously, in every case in which the jury is permitted to do its job -- regardless of whether the outcomes in any range of cases are the same -- this core function is consistently carried out. "[A]t times the law may not require one action or decision only, but instead permits a particular range of choices"; even where "discretion is exercised in different ways on identical facts . . . there is still *legal* consistency . . . [which] results from the very fact that the law permits a range of choices." *Id.* at 1001-02 (emphasis in original). As Justice Kennedy emphasized in *Haslip*, the institution of jury trial naturally assumes and respects the discretion of juries to reach inconsistent *outcomes* in separate cases as the price of ensuring a consistent adjudicative *process*.

Ironically, the Sixth Circuit itself once recognized this central principle in reviewing the results of the 1985 multi-district common issues trial that resolved over 800 Bendectin cases, *In*

re Richardson-Merrell, Inc. "Bendectin" Products Liability Litigation, 624 F. Supp. 1212 (S.D. Ohio 1985), *aff'd*, 857 F.2d 290 (6th Cir. 1988), *cert. denied*, 488 U.S. 1006 (1989). In that trial the jury happened to find against the plaintiffs on causation. But the trial judge recognized that "[b]oth sides presented testimony of eminently qualified and highly credible experts who differed in regard to the safety of Bendectin" and that the jury was confronted with "assess[ing] the credibility of each witness [to] resolve all conflicts of fact." 624 F. Supp. at 1244. The Sixth Circuit agreed that "the jury verdict following trial here might have been for the plaintiffs instead of for the defendant." 857 F.2d at 325.

In the decision below the Sixth Circuit utterly renounced its earlier recognition that a jury could legitimately decide either way on causation. The Lees were part of the 1985 multi-district class action for pretrial purposes but they exercised their right under Fed. R. Civ. P. 26(b)(3) to opt-out of the class action in favor of an individual trial conducted by counsel of their choice. But in the case at bar the Sixth Circuit forced them and all future Bendectin plaintiffs into a new, "pseudo-class action," one stripping away most of the features of a normal lawsuit. The Lees' opt-out right was nullified because they were held, for consistency's sake, to the same result reached in the multi-district trial. In this pseudo-class action Bendectin plaintiffs may not have the credibility of complex conflicting scientific testimony resolved by a jury, as Congress provided in enacting Rules 702-05 of the Federal Rules of Evidence. Rather, appellate judges weigh the credibility of testimony on causation. Nor do these plaintiffs have the right to a judicial hearing to resolve the factual issues on their own record. They are told that the factual issues have already been considered through the proxy of other litigants in an earlier case -- *Turpin* -- and that efficiency and consistency demand that they be bound by the earlier factual assessment, even though they were not parties to the earlier action and were not in privity to a party. *Compare Martin v. Wilks*, 109 S. Ct. 2180, 2184-88 (1989); *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 329 (1971); *Chase National Bank v. Norwalk*, 291 U.S. 431, 441 (1934).

Moreover, the factual finding of scientific truth from the earlier action is applied without regard to the stringent limits on judicial notice and the procedural safeguards mandated by Congress in Fed. R. Evid. 201. *See* page 8, *supra*.

With its willingness to adopt and enforce its own presumptive rules about what kinds of expert testimony are sufficiently persuasive to be heard by a jury, it is difficult to guess the next task the Sixth Circuit may take on for itself. If the course taken in *Turpin* and in the decision below were permitted to stand, then there would be no discernable limit to the types of sweeping rules that a court might adopt according to its own freewheeling assessment of scientific truth: Perhaps tomorrow courts would promulgate a list of certain chemicals that have been "found" by judges to be carcinogens, and permit any plaintiff who can prove that he or she was exposed to one of the chemicals on the list to recover damages, unless the defendant can make some extraordinary showing that the chemical is safe. Perhaps the next day the federal courts would decide that eyewitness testimony is, on the whole, an unsatisfying evidentiary method that tends to be overvalued by jurors, and would thereafter bar such testimony in any criminal case in which a judge determines that it is contradicted by the weight of opposing evidence.

The fundamental constitutional, statutory and rule-based constraints barring the *Turpin* approach were lost on the court below as it reinvented the civil justice system to take decision of difficult, complex scientific issues in commonly litigated cases away from the jury, and substitute its own analysis of the credibility of competing experts. The Sixth Circuit is not the first to lose its way. In *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166, *reh'g denied*, 884 F.2d 167 (5th Cir. 1989), *cert. denied*, 110 S. Ct. 1511 (1990), the Fifth Circuit confronted the problem of inconsistent Bendectin verdicts with a solution even more expansive of the Judicial power and invasive of the jury system. "Mass tort" cases, the Fifth Circuit wrote, "present special problems and challenges to traditional ideas regarding the role of the jury as a decisionmaker." *Id.* at 309. The problem with Bendectin and

other similar cases, it announced, is that "there is often no consensus in the medical community about whether a given substance" causes birth defects, and therefore "juries often split both ways the issue," thus creating in drug manufacturers "uncertainty which can tend to produce a sub-optimal amount of new drug development." *Id.* at 309-10. The solution imposed by the Fifth Circuit was much like that imposed by the Sixth Circuit: regardless of the content of governing rules of evidence and procedure, for this class of cases "courts must critically evaluate the reasoning process by which the experts connect data to their conclusions in order for courts to *consistently* and *rationally* resolve the disputes before them." *Id.* at 310 (emphasis added). To achieve consistency and rationality, the Fifth Circuit ruled that unless and until a Bendectin plaintiff could produce an epidemiological study exhibiting "statistical significance" -- that is, suggesting a link between Bendectin and birth defects with 95% confidence -- no plaintiff could recover anywhere in the Fifth Circuit. *Id.* at 311-15.

A number of lower federal court judges have, of course, rebelled from cases like *Brock*, the Sixth Circuit decision below, and similar attempts to reinvent the civil justice system, revealing a conflict in the circuits that provides rich material for this Court's consideration of the fundamental issues involved here. For example, in *Brock* itself six judges, including Judge Patrick Higginbotham, dissented from denial of rehearing *en banc*; among other things they were puzzled over "what is left in this circuit of . . . the Seventh Amendment right to trial by jury." 844 F.2d at 168.

In *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3d Cir. 1990), also a Bendectin case, the court stated that it understood and sympathized "with the concerns expressed in *Brock* over the costs and inequities that flow from inconsistent outcomes in Bendectin cases, the potential effect erroneous verdicts have on the availability of useful medicines, and the wastefulness of continued reconsideration of an identical scientific issue in the courts." *Id.* at 951-52. However, the Third Circuit clearly recognized that it could not attempt to solve

these policy problems through exercise of its inherent judicial power or through manipulation of the rules laid down by Congress and by this Court:

> . . . [W]e do not have authority to create special rules to address the problems posed by continued Bendectin litigation. Principles of issue preclusion have not developed to the point where we may bind plaintiffs by the finding of previous proceedings where they are not parties . . . . Nor are we at liberty, especially in a case to be decided under our diversity jurisdiction, to impose different burdens of proof on Bendectin plaintiffs than those that would apply in analogous products liability suits.

Id. at 952.

Finally, Judge Patrick Higginbotham, writing for the Fifth Circuit, honored the limits on the role defined for the courts in the context of the far more burdensome asbestos litigation, in *In re Fibreboard Corp.*, 893 F.2d 706 (5th Cir. 1990). He rejected a district court's attempt to impose on defendants a quasi-administrative dispute-resolution scheme that extrapolated from the average results of early "test" cases and which would have denied the defendants their Seventh Amendment and due process rights in thousands of cases, thereby warping the applicable state tort law policy choices in violation of the *Erie* doctrine. In answer to the district court's plea that this innovative scheme was essential to solving a docket crisis facing the courts, Judge Higginbotham suggested that the representative branches be consulted instead, and stated: "The Judicial Branch can offer the trial of lawsuits. It has no power or competence to do more." *Id.* at 712.

The willingness of the Sixth Circuit below, like that of the Fifth Circuit in *Brock*, to employ inherent judicial power in the exercise of its *diversity jurisdiction* to force a consistent result in Bendectin cases with no regard for the underlying state law is a shocking violation of this Court's *Erie* jurisprudence. Both rules -- the Sixth Circuit's rule that epidemiological studies are not especially probative, combined with its requirement that to pass the summary judgment stage a Bendectin plaintiff must come up

with an especially cogent and thorough analysis of available animal studies; and the Fifth Circuit's completely opposite rule that a Bendectin plaintiff must come up with "statistically significant" epidemiological studies, because animal studies are almost worthless -- obviously have *no relation at all* to the substantive law of the several states covered within each circuit. Indeed, in its *Turpin* opinion the Sixth Circuit cited not a single case on controlling Kentucky law; in its decision below, the Sixth Circuit was similarly silent on controlling Tennessee law. The effect of these rules is to create special presumptions or burdens of proof barring a finding of liability until a unique quantum of proof can be mustered by a plaintiff; the rules are clearly "substantive" within the meaning of the *Erie* doctrine. *See, e.g.*, *Dick v. New York Life Ins. Co.*, 359 U.S. 437, 446-47 (1959); *Cities Service Oil Co. v. Dunlap*, 308 U.S. 208 (1939).[3]

The creation of such special presumptions and burdens flys in the face of *Erie* and the Rules of Decision Act, which together "mandate[] that a federal court sitting in diversity apply the substantive law of the forum State, absent a federal statutory or constitutional directive to the contrary." *Salve Regina College v. Russell*, 111 S. Ct. 1217, 1218 (1991) (citing *Erie*, 304 U.S. at 78; 28 U.S.C. § 1652 (Rules of Decision Act)). Because the decision below permits Merrell to eviscerate all future Bendectin cases filed in the states of Kentucky, Ohio, Michigan and Tennessee, merely by removing them to federal court in the Sixth Circuit, it violates *Erie*'s "twin aims" of discouraging forum-shopping and avoiding inequitable administration of the laws. *See Chambers*, *supra*, 111 S. Ct. 2123, 2137 (1991) (majority opinion). *See also id.* at 2148-49 (Kennedy, J., dissenting); *Stewart Organization, Inc. v. Ricoh Corp.*, 108 S. Ct. 2239, 2248-50 (1988) (Scalia, J., dissenting).

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[3] Tennessee specifically bars any such special rules for medical causation. *See* Tenn. Code Ann. § 24-7-114 (1991). *See also Johnson v. Schevenell Ready Mix, Inc.*, 608 S.W.2d 582, 584 (Tenn. 1980); *Combustion Engineering, Inc. v. Kennedy*, 562 S.W.2d 202, 203-04 (Tenn. 1978); *Vandergriff v. Bituminous Casualty Corp.*, 692 S.W.2d 20, 22 (Tenn. 1985); *Ledford v. Moskowitz*, 742 S.W.2d 645, 649 (Tenn. App. 1987).

Indeed, the inequitable results spawned by the decision below reveal that it is the Fifth and Sixth Circuits -- not any succession of juries -- that is guilty of breeding inconsistency. In the short time since the Sixth Circuit handed down its *Turpin* ruling, the courts of Michigan (within the Sixth Circuit region) have ruled that a Bendectin case could go forward over a sufficiency-of-evidence objection by Merrell (*see* Appendix E, at A53). Later, a trial court in Texas (within the Fifth Circuit region) entered judgment against Merrell in another Bendectin case (*see* Appendix F, at A57). Because state courts remain open to many Bendectin plaintiffs, as long as courts like the Fifth and Sixth Circuits persist in adhering to *ad hoc* doctrines to rid their dockets of such cases, and as long as the lessons of *Erie* remain lost on such courts, the differences between the results reached in federal and state courts will increase and the quest for consistency of adjudication will ironically become ever more quixotic. Only prompt intervention by this Court can ensure that procedural regularity and fundamental constitutional values will prevail over growing judicial confusion in the federal courts.

CONCLUSION

For all these reasons, certiorari should be granted.

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APPENDIX A

UNITED STATES COURT OF APPEALS
For the Sixth Circuit

No. 91-5369

RONNIE LEE and MACKEY LEE,
Individually and as Parents and
Natural Guardians of MICHAEL LEE, a Minor,

Plaintiffs-Appellants,

v.

RICHARDSON-MERRELL, INC.,
A Delaware corporation,

Defendant-Appellee.

On Appeal from the United States District
Court For the Western District of Tennessee

(April 22, 1992)

NOTICE: NOT RECOMMENDED FOR FULL-TEXT PUBLICATION. SIXTH CIRCUIT RULE 24 LIMITS CITATION TO SPECIFIC SITUATIONS. PLEASE SEE RULE 24 BEFORE CITING IN A PROCEEDING IN A COURT IN THE SIXTH CIRCUIT. IF CITED, A COPY MUST BE SERVED ON OTHER PARTIES AND THE COURT. THIS NOTICE IS TO BE PROMINENTLY DISPLAYED IF THIS DECISION IS REPRODUCED.

BEFORE: MARTIN and SUHRHEINRICH, Circuit Judges; and PECK, Senior Circuit Judge.

PER CURIAM. This is an appeal in a diversity action brought under Tennessee law by plaintiffs Ronnie and Mackey Lee on behalf of their minor child, Michael Lee, against defendant Richardson-Merrell, Inc. ("Merrell"). The Lees contend that Michael's birth defect, a limb reduction defect, was caused by his mother's ingestion during pregnancy of the Merrell product Bendectin. The district court granted summary judgment in favor of Merrell. We affirm.

The plaintiffs allege that Mackey Lee ingested the anti-nausea drug Bendectin on or about September 21, 1973, when she was about seven weeks pregnant with Michael Lee. Michael was born on March 27, 1974, with various limb deformities characterized by shortness and webbing of his fingers and generalized smallness of his hands. The Lees assert that Mackey Lee ingested no other drugs during this period of time and that Michael's birth defects are not genetic. The plaintiffs submit that Mackey Lee's ingestion of Bendectin during the time that Michael's limbs were beginning to develop was the proximate cause of Michael's birth defects.

Merrell filed a motion for summary judgment alleging that all relevant epidemiological studies indicate that there is no statistically significant link between the use of Bendectin and the type of birth defects suffered by Michael Lee. Merrell asserted that these human epidemiological studies comprised the only competent evidence on the issue of whether Bendectin is a teratogen (a substance capable of causing birth defects).

The Lees submitted contrary scientific testimony which concluded that Bendectin was a teratogen based on (1) chemical structure analyses of Bendectin's antihistamine component, doxylamine succinate; (2) *in vitro* (test tube) studies; (3) *in vivo* (animal) studies; and (4) criticism and reanalysis of various epidemiological studies submitted by Merrell. The Lees argued that their scientists possessed the requisite "knowledge, skill, training, education, and experience" to qualify as experts and that their opinions were based on "the type of data generally and reasonably relied upon by experts in the particular field."

After a thorough review of the proffered testimony, the district court determined that the Lees had not produced sufficient evidence of causation to preclude summary judgment. This appeal followed.

The Lees offered the opinion of seven experts to establish that Bendectin was a teratogen and that Mackey Lee's ingestion of Bendectin caused Michael Lee's birth defects. These scientists possess expertise in fields ranging from developmental biology and reproductive epidemiology to biostatistics and pharmacology. Collectively, the Lees' experts would offer testimony concluding that to a reasonable degree of certainty Bendectin is associated with limb defects.

In response to this expert testimony, defendant Merrell submits that human epidemiological studies demonstrate an absence of any significant causal link connecting Bendectin use with birth defects. To support this position, Merrell submitted summaries of over thirty epidemiologic studies, none of which demonstrate a connection between Bendectin and birth defects.

As noted above, the Lees' experts rely on chemical structure analyses of doxylamine succinate, in vitro and in vivo studies and reanalyses of human epidemiological data. We conclude that a finding of a casual relationship between Bendectin use and Michael Lee's birth defects based upon this evidence would be conjectural at best in light of this court's recent opinion in *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, No. 90-5690 (6th Cir. March 11, 1992). In *Turpin*, another panel of this court reviewed the scientific data on Bendectin in great detail and concluded that the evidence presented by the plaintiffs' experts fell short of showing that "Bendectin more probably than not causes limb defects in children born to mothers who ingested the drug at prescribed doses during pregnancy." Slip op. at 24.

The evidence presented by the Lees in the instant case is identical in all material respects to the evidence relied upon by the plaintiffs in *Turpin*. *Compare* Jt. App. 2040-2092 (Affidavits of Drs. Glasser, Gross, Crescitelli and Swann) *with Turpin*, slip op. 9-22 (identical testimony by affidavit). The plaintiffs'

experts in both cases are the same. In both cases, the experts reach their conclusions based upon their reanalyses of prior epidemiological studies and the use of animal studies to predict Bendectin's teratogenic effects in human beings. For the reasons stated in *Turpin*, we view this testimony as unable to bridge "the analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue of human birth defects. . . ." Slip op. at 24. In short, the plaintiffs' scientific evidence, taken as whole, fails to create a genuine issue of material fact. Consequently, summary judgment for the defendant on the issue of causation was appropriate. *See Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1479 (6th Cir. 1989) (respondent must produce evidence supporting every essential element of his or her case to prevent summary judgment).

We have examined the entire record in this case and we can find no material difference between this case and *Turpin*. We further find that without such evidence the plaintiffs cannot prove that Michael Lee's birth defects were caused by his mother's ingestion of Bendectin. Given this conclusion we need not address Merrell's remaining arguments or the district court's alternative holding excluding plaintiffs' evidence. Accordingly, for the reasons as fully stated in this court's opinion in *Turpin*, the district court's grant of summary judgment in favor of defendant Merrell is AFFIRMED.

APPENDIX B

UNITED STATES DISTRICT COURT
For the Western District of Tennessee,
Western Division.

No. 84-2228 GB

RONNIE LEE, et al.,

Plaintiffs,

v.

RICHARDSON-MERRELL, INC.,

Defendant.

(January 30, 1991)

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

GIBBONS, District Judge.

Before the court is the motion for summary judgment of defendant Merrell Dow Pharmaceutical Inc. (formerly Richardson-Merrell, Inc.). Plaintiffs Ronnie and Evonne Mackey Lee sue on behalf of their minor child, Michael Lee, to recover damages for birth defects that allegedly resulted from Mrs. Lee's ingestion of the anti-nausea prescription drug Bendectin, manufactured by defendant,[1] while she was pregnant with Michael.

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[1] Defendant manufactured and marketed Bendectin from 1956 to 1983. In 1983, faced with costly litigation involving use of the drug, it voluntarily withdrew the drug from the market.

The issue raised by the summary judgment motion is whether plaintiff's evidence is sufficient to create a genuine issue of material fact on the causation issue.

Plaintiffs allege that around September 21, 1973, Mrs. Lee, who was about seven weeks pregnant, took Bendectin. Michael Lee was born on March 27, 1974, with limb defects -- shortness of his fingers, "webbing" and generalized smallness of his hands. Plaintiffs allege that Mrs. Lee ingested no other drugs during this period of time and that no other substance caused or contributed to Michael Lee's limb defects. In addition, plaintiffs allege that Michael's defects are not genetically related. Finally, plaintiffs allege that Mrs. Lee's ingestion of Bendectin, at the point in pregnancy that the extremities are beginning to develop, was the proximate cause of Michael's limb defects.

Both plaintiffs and defendant have submitted expert opinion evidence to the court in the form of affidavits, depositions, and prior trial testimony. Several of plaintiffs' experts offer an opinion that the ingestion of Bendectin by Mrs. Lee caused Michael Lee's birth defects. The issue therefore is not whether plaintiffs' can present any expert proof on the issue of causation. Rather, the issue is whether plaintiffs expert proof on causation creates a genuine issue of material fact, in view of the bases for the opinions of plaintiffs' experts.

Defendant asserts that human epidemiology studies comprise the only competent evidence on the question of Bendectin's teratogenicity, or ability to cause birth defects. More than thirty such studies have found no causal connection between Bendectin and birth defects. Defendant argues that plaintiffs' proffered expert testimony is inadmissible under Federal Rules of Evidence 702 and 703, because the opinions of plaintiffs' experts are not "in conformity to a generally accepted explanatory theory," *United States v. Kozminski*, 821 F.2d 1186, 1201 (6th Cir. 1987), and are not based on facts or data "of a type reasonably relied upon by experts in the particular field." Fed.R.Evid. 703. Plaintiffs' experts base their opinions on *in vivo* testing in animals, *in vitro* testing on isolated cells and tissue, and human

data (which includes criticism and reanalysis of various epidemiological studies submitted by defendant and additional studies).

Federal Rule of Civil Procedure 56 provides that a motion for summary judgment shall be granted if, based on the record as a whole, there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. In a motion for summary judgment, the moving party bears the burden of clearly establishing the non-existence of any genuine issue of material fact, and the evidence as well as the inferences drawn therefrom must be read in the light most favorable to the non-moving party. *Kochins v. Linden-Alimack, Inc.*, 799 F.2d 1128, 1133 (6th Cir. 1986).

According to Rule 56(e) of the Federal Rules of Civil Procedure, when confronted with a properly supported motion for summary judgment, the non-moving party must "set forth specific facts showing that there is a genuine issue for trial." A genuine issue of material fact exists "if the evidence [presented by the non-moving party] is such that a reasonable jury could return a verdict for the non-moving party." *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 248, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986).

In a motion for summary judgment, the non-moving party must "go beyond the pleadings and by [his] own affidavits, or by the 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" *Celotex Corp. v. Catrett*, 477 U.S. 317, 324, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986) (quoting Fed. R. Civ. P. 56(e)). "The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff." *Anderson*, 477 U.S. at 252. The party opposing summary judgment "must do more than simply show there is some metaphysical doubt as to the material facts," *Matsushita Electrical Industrial Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586, 89 L. Ed. 2d 538, 106 S. Ct. 1348 (1986), but instead must present "concrete evidence supporting its claims and

establishing the existence of a genuine issue of fact." *Cloverdale Equipment v. Simon Aerials Inc.*, 869 F.2d 934, 937 (6th Cir. 1986). In essence, the inquiry is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson*, 477 U.S. at 252.

Federal Rule of Evidence 702 provides that "if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise." The United States Court of Appeals for the Sixth Circuit in *United States v. Green*, 548 F.2d 1261 (6th Cir. 1977), enunciated the standard for admissibility of expert testimony under Rule 702: (1) a qualified expert must be offered; (2) the expert must testify on a proper subject; (3) he must testify in conformity to a generally accepted explanatory theory; and (4) the probative value of the testimony must outweigh any prejudicial effect. *Id.* at 1268.

This standard was reaffirmed by the Sixth Circuit in the case of *United States v. Kozminski*, 821 F.2d 1186 (6th Cir. 1987). *See also Novak v. United States*, 865 F.2d 718, 721 (6th Cir. 1989) (applying test in a civil action). The *Kozminski* court elaborated that the third element of the test, "conformity to a generally accepted explanatory theory," must be firmly anchored in sound, reliable, and sufficiently accurate scientific principles. *Id.* at 1201. The court stated that scientific explanatory theory must have: (a) received at least some exposure within the scientific peerage to which it belongs; (b) been subjected to peer evaluation to determine its scientific validity and reliability; and (c) achieved general acceptance within the scientific community to which it belongs. *Id.* at 1201.

Rule 703 requires that the data relied upon in the formulation of an expert opinion be of "a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." Fed. R. Evid. 703. Thus, if expert opinion

is not based upon data of "a type reasonably relied upon by experts in the particular field," the expert fails to be helpful, but, rather, is confusing or misleading. *See Daubert v. Merrell Dow Pharmaceutical, Inc.*, 727 F. Supp. 570, 572 (S.D. Cal. 1989). "Whether an expert's opinion has an adequate basis, and whether without it an evidentiary burden has been met, are matters of law for the court to decide." *Richardson v. Richardson-Merrell*, 649 F. Supp. 799 (D. D.C. 1986), *aff'd*, 273 App. D.C. 32, 857 F.2d 823, 829 (D.C. Cir. 1988), *cert. denied*, ___ U.S. ___, 110 S.Ct. 218, 107 L.Ed.2d 171 (1989).

The first category of data on which plaintiff's experts rely is *in vivo* (animal) studies. In this category are opinions reflected in the affidavits of Drs. Adrian Gross, Frederick Crescitelli and John Palmer. Plaintiffs' Response, p. 53. Dr. Gross, a veterinarian, states that, based upon animal studies, the doxylamine succinate component of Bendectin is in fact a teratogen.[2] Affidavit of Adrian Gross filed in *Daubert*, Plaintiffs' Attachment 41. Dr. Crescitelli, a biologist, also states that doxylamine succinate is a teratogen. Affidavit of Frederick Crescitelli filed in *Daubert*, Plaintiffs' Attachment 39. Dr. Palmer, a physician and pharmacology professor, avers that, based upon animal studies, *in vitro* studies, and pharmacological data, Bendectin is a teratogen. Affidavit of John Palmer filed in *Elkins*, Plaintiffs' Attachment 43. Plaintiffs also assert, without accompanying evidence, that several other experts would testify similarly at trial.

Second, plaintiffs rely on *in vitro* studies to support their position. *In vitro* studies are studies conducted in test tubes or petri dishes. Plaintiffs' experts relying on this type of study are Drs. Stewart Newman, Shanna Swan, Crescitelli and Palmer. Plaintiffs' Response, p. 57. Dr. Newman, a developmental biologist, asserts in his affidavit and in prior trial testimony that,

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[2] Bendectin has three components: dicyclomine hydrochloride, an antispasmodic drug; doxylamine succinate, an antihistamine; and pyridoxine (vitamin B6).

based upon *in vitro* studies, Bendectin is a teratogen. Affidavit of Stuart Newman filed in *Elkins*, Plaintiffs' Attachment 42; trial testimony of Newman in *Ealy*, Plaintiffs' Attachment 18.

Dr. Swan, an epidemiologist and biostatistician practicing in the field of reproductive epidemiology, states that to a reasonable degree of certainty, considering all available data provided in animal, *in vitro*, and epidemiological studies, Bendectin is associated with limb reduction defects. Affidavit of Shanna Swan filed in *Daubert*, Plaintiffs' Attachment 40. Dr. Swan bases her opinion on "the methodology that is generally and reasonably relied upon by epidemiologist to analyze, study and interpret data that has been collected, published and unpublished in trying to draw opinions concerning whether or not there is a cause and effect relationship between a drug and a birth defect." *Id.*.

Finally, plaintiffs offer some of their own "relevant human data" on the teratogenicity of Bendectin. Plaintiffs direct the court's attention to the affidavits of Drs. Jay Glasser and Swan and to their prior testimony in similar litigation. *See* Plaintiffs' Attachments 10, 29, 38, and 40. Dr. Glasser, a specialist in biostatistics, epidemiology and biometry, asserts that Bendectin is associated with congenital disorders, including limb defects, within a reasonable degree of epidemiological certainty. Affidavit of Jay Glasser filed in *Daubert*, Plaintiffs' Attachment 38. Dr. Glasser states that his opinion is based on techniques that are generally and reasonably relied upon by biometrists, epidemiologist and biostatisticians. *Id.* Plaintiffs also rely on various studies and articles. *See* discussion *infra* at 9-10.

Based on these three categories of evidence, plaintiffs argue that their experts have the requisite "knowledge, skill, training, education, [and] experience" and that "the data that they were relying on was of the type that was generally and reasonably relied upon by experts in the particular field." Response at 30. The court finds, however, that plaintiffs' expert evidence fails to meet the test for admissibility enunciated by the Sixth Circuit in *Green* and *Kozminski* or the requirements of Rule 703, in view

of the overwhelming contrary epidemiological data supporting the non-teratogenicity of Bendectin. Given the extensive human studies of Bendectin that fail to establish that Bendectin can cause birth defects, experts cannot reasonably rely on *in vivo* and *in vitro* studies that support a contrary finding. Nor can opinions based on *in vivo* and *in vitro* studies be considered "in conformity to a generally accepted explanatory theory," in view of the overwhelming evidence from human studies.

The deficiencies of plaintiffs' evidence based on *in vivo* and *in vitro* studies are apparent, when compared specifically with the data on which the opinions of defendant's experts are based. The opinions of defendant's experts are based on a large number of studies -- more than thirty. Data on more than 130,000 women and children was considered in the studies. No study has found a causal association between Bendectin and birth defects.

In addition, the Food and Drug Administration's (FDA) constant reexamination of the safety of Bendectin has reaffirmed Bendectin's safety. A 1979 FDA TALK PAPER stated:

> Because of the extensive use of this drug, FDA over the years has carefully monitored it, with a particular view to its effect on the fetus. In the studies to date, there is no evidence that Bendectin is associated with an increased risk of birth defects.

The FDA again affirmed Bendectin's safety in a 1980 TALK PAPER, and in a 1982 TALK PAPER the FDA, in response to a then recently released animal study, concluded:

> The significance of both the rat and monkey studies, even if reproducible, would be debatable in view of the more pertinent human epidemiologic data that have not, to date, produced convincing evidence that Bendectin causes diaphragmatic hernias or other birth defects in the offspring of women treated with Bendectin.

Plaintiffs' "relevant human data" comes no closer to meeting the test for admissibility than the opinions based on *in vivo* and *in vitro* studies. To the extent that this data consists of the

affidavits of experts, these affidavits are based on data on which the experts could not "reasonably rely," and the opinions of the experts do not conform to a "generally accepted explanatory theory." The remainder of this data, consisting of articles and studies, simply fails to support plaintiffs' position. For example, plaintiffs rely on an article from the *Canadian Medical Association Journal* by a P. Banister.[3] Referring to this article, plaintiffs represent that "in a study involving 29 mothers who used drugs during a pregnancy and given birth to a child with limb defects, three had used Bendectin, all the first trimester." Examination of the Banister study in fact reveals that the study was unable to "establish the etiology of the anomalies", and that "no currently recognized factor has been identified for the majority of these cases and that there is a great need for further detailed investigation of possible etiological factors." Banister Article, Plaintiffs' Attachment 30.

Plaintiffs also refer to a study published by the Birmingham Research Units of the Royal College of General Practitioners.[4] Although plaintiffs state that the data compiled in the study showed a statistical association between antihistamines and birth defects, a closer look at the article reveals that "[i]n a prospective study involving 9,000 pregnant women, no cause-and-effect relationships have been established between morbidity recorded or drugs taken during early pregnancy and subsequent congenital malformations. It is also very unlikely that any drug in common use in 1964 had even a minor influence on congenital malformations recognizable, in the first six weeks of life." Birmingham Article, Plaintiffs' Attachment 30.

Plaintiffs submitted thirteen additional articles involving human

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[3] Banister, P., *Congenital Malformations: Preliminary Report of an Investigation of Reduction Deformities of the Limbs, Triggered by a Pilot Surveillance System*, Cand.Med.Ass.J. 103:466-72 (1970).

[4] Birmingham Research Unit of the Royal College of General Practitioners, *Morbidity and Drugs in Pregnancy*, Journal of the Royal College of General Practitioners, 25, 631-645 (1975).

data, not one of which supports plaintiffs' theory that Bendectin causes limb defects. There is simply no epidemiological evidence supporting plaintiffs' theory of causation.

This court's conclusion about the opinions of plaintiffs' experts is consistent with that of many other courts which have considered this same issue in Bendectin cases. The First, Fifth and D.C. Circuit Courts of Appeals and numerous district courts, including the United States District Court for the Eastern District of Kentucky, have held that there is insufficient admissible evidence that Bendectin can cause birth defects to submit the issue to a jury.

In *Lynch v. Merrell-National Laboratories*, 646 F. Supp. 856 (D. Mass. 1986), *aff'd*, 830 F.2d 1190 (1st Cir. 1987), plaintiffs relied upon *in vivo* studies to support their position of Bendectin's teratogenicity. In granting summary judgment for defendants, the district court found the animal studies lacking probative value and therefore inadmissible. *Id.* at 866. In *Lynch*, plaintiff's own expert, Dr. Alan Done, admitted that the fact that Bendectin may be teratogenic in a species of animal does not necessarily mean it will be teratogenic in humans. *Id.* at 865. Dr. Michael Melnick had testified that, on the basis of animal studies, "one can only speak of birth defects in the animal -- in the animal one has studied." *Id.* The *Lynch* court also found it difficult to extrapolate findings from animal studies to human studies because of the large doses used in the animal studies. *Id.* Dr. William Scott had testified that almost any substance can be shown to be teratogenic at some dose in some species. *Id.*

The *Lynch* court also commented on the evidence of *in vitro* studies submitted to it.

> The *in vitro* studies suffer from the same deficiencies as the *in vivo* animal studies, they are performed on other biological species and at doses far in excess of the human therapeutic dose. This court also cannot find, pursuant to Rule 703, that such studies are "of a type reasonably relied upon by experts in the particular field."

Lynch, 646 F. Supp. at 866.

The First Circuit affirmed the lower court's ruling that plaintiff failed to present sufficient proof of causation to permit a reasonable trier of fact to conclude that Bendectin had caused the birth defect of the plaintiff. The court stated that *in vivo* studies, *in vitro* studies, and the study of "analogous" chemicals, singly or in combination, "do not have the capability of proving causation in human beings in the absence of any confirmatory epidemiological data." *Lynch*, 830 F.2d at 1194.

The Fifth Circuit, in *Brock v. Merrell Dow*, 874 F.2d 307, *mod.* 884 F.2d 166 (5th Cir. 1989), *cert. denied*, ___ U.S. ___, 110 S. Ct. 1511 (1989), reversed a jury verdict for plaintiffs, holding that the lack of conclusive epidemiological proof was fatal to the plaintiffs' case. Plaintiffs' experts in *Brock* included Drs. Newman, Glasser and Thiersch, all of whom are plaintiffs' experts in the present case. With regard to animal studies the *Brock* court found:

> Other plaintiffs' experts conducted animal tests and reanalyses of previously performed animal tests. Drs. Thiersh and Glasser both reanalyzed results of previous studies on animals. Both admitted that the results of their animal studies are difficult to extrapolate to humans. Dr. Thiersch admitted in his deposition that one must rely, in part, on epidemiological studies to determine whether a substance is toxic in humans. Similarly Dr. Glasser admitted that the only way to tell whether a substance is teratogenic in humans is to look to the human experience.

Id. at 314.

One of the most persuasive opinions with regard to plaintiffs' evidence in a Bendectin case comes from *Richardson*, where the D.C. Circuit affirmed the trial judge's holding that the evidence presented at trial was insufficient to support the jury's determination that Bendectin caused the minor-plaintiff's limb reduction defects. With regard to the probative value of the types of data relied upon by plaintiff's expert, Dr. Alan Done, the court

stated:

> These three types of studies then -- chemical, *in vitro*, and *in vivo* -- cannot furnish a sufficient foundation for a conclusion that Bendectin caused the birth defects at issue in this case. Studies of this kind, singly or in combination, are not capable of proving causation in human beings in the face of the overwhelming body of contradictory epidemiological evidence. Perhaps mindful of this, the last type of evidence considered by Dr. Done consisted of epidemiological studies. When such studies are available and relevant, and particularly when they are numerous and span a significant period of time, they assume a very important role in determinations of questions of causation.

Richardson, 857 F.2d at 830. In rejecting Dr. Done's epidemiological data, the court stated:

> Dr. Done further admitted that no one who has published work on Bendectin has concluded that there is a statistically significant association between Bendectin and limb reduction defects of the type at issue in this case. Only by recalculating the data was Dr. Done able to obtain what he deems a statistically significant result. Moreover, the studies rejected by Dr. Done had been published in peer-reviewed scientific journals, while Dr. Done has neither published his recalculations nor offered them for peer review.

Id. at 831.

Recently, in a well-reasoned order Judge Eugene Siler, Jr., of the United States District Court for the Eastern District of Kentucky, in the case of *Gary Turpin, et al. v. Merrell Dow Pharmaceutical Inc.*, 736 F. Supp. 737 (decided 1990). Defendant's Exhibit 10, p. 17, granted summary judgment in favor of defendant Merrell-Dow. The court stated, "in light of over thirty (30) epidemiological studies concluding that no statistically significant association exists between Bendectin and human birth defects, and after closely scrutinizing the bases of the proffered opinions of the plaintiffs' experts, this court concludes that the

testimony is inadmissible under Fed. R. Evid. 703." *Id.* In finding plaintiffs' evidence to be inadmissible the court applied the four part test set out in *Kozminski* and concluded:

> The plaintiffs' experts' testimony while satisfying three prongs of the test, fails the third prong in that their testimony is not in conformity with a generally accepted explanatory theory in light of the overwhelming epidemiological data governing the non-teratogenicity of Bendectin.

Id. Plaintiffs' experts in *Turpin* included Drs. Thiersch, Swan, Newman, Gross, Glasser, Crescitelli, and Palmer, all of whom are plaintiffs' experts in the instant litigation.

Quite obviously, the affidavits and former trial testimony of experts submitted by plaintiffs in this case were considered in other cases. Substantially identical testimony has been rejected in *Lynch* (Dr. Swan), *Brock* (Drs. Newman, Glasser and Thiersch), *Ealy* (Drs. Gross, Newman, Swan, Thiersch), and most recently *Turpin* (Drs. Thiersch, Swan, Newman, Crescitelli, Gross, Glasser, and Palmer). Other courts have examined plaintiffs' evidence in the context of a motion for summary judgment or motion for judgment notwithstanding the verdict and found it to be insufficient. *See e.g., Hull v. Merrell Dow Pharmaceutical Inc.*, 700 F. Supp. 28 (S.D. Fla. 1988); *DePyper v. Navaro*, No. 83-303-467NM (Civ. Ct. Wayne Co., Mich. March 10, 1990); *Koller v. Richardson-Merrell, Inc.*, No. 80-1258 (June 30, 1989, D.D.C.) and *Ambrosini v. Richardson-Merrell, Inc.*, No. 86-278 (June 30, 1989, D.D.C.) (Defendant's Exhibits 17 and 18) (granting summary judgment for defendant relying on *Richardson*); *DeLuca v. Merrell Dow Pharmaceutical Inc.*, No. 87-226 (1989 D.N.J.) (Defendant's Exhibit 19); *Monahan v. Merrell-National Laboratories*, No. 83-3108-WP (December 18, 1987, D. Mass.) (Defendant's Exhibit 20); *Daubert v. Merrell Dow Pharmaceutical Inc.*, 727 F. Supp. 570

(S.D. Cal. 1989).[5]

The court finds that plaintiffs' expert evidence would not be admissible at trial and therefore cannot be considered in connection with the motion for summary judgment. Fed.R.Civ.P. 56(e). Therefore, plaintiffs have failed to offer sufficient evidence to create a genuine issue of material fact on the causation issue. The motion for summary judgment is granted, and judgment shall be entered for defendant.

IT IS SO ORDERED.

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[5] In support of plaintiffs' position are *Oxendine v. Merrell-Dow*, 506 A.2d 1100 (D.C. 1986) (*Oxendine I*) and *Oxendine v. Merrell-Dow*, 563 A.2d 330 (D.C. 1989) (*Oxendine II*). *Oxendine* allowed the introduction of expert opinion viewing the recalculations of epidemiological studies and the varying conclusions as involving a "classic battle of the experts". *Oxendine*, 506 A.2d at 1110. The D.C. Circuit, however, specifically rejected the reasoning in *Oxendine*, noting the differences between state and federal rules of evidence regarding admissibility. *Richardson*, 857 F.2d at 825 n. 9.

Plaintiffs cite other authority in their response to defendant's motion to dismiss (Response at 34-41). On occasion, however, they fail to give a full picture of this authority. For example, in their response plaintiffs cite *Ealy v. Richardson-Merrell, Inc.* and leave the court with the impression that, after a verdict for plaintiffs, the trial judge denied defendant's motion for judgment notwithstanding the verdict. Although this is true, plaintiffs fail to inform the court that the D.C. Circuit reversed the lower court on the issue of liability, holding plaintiffs' evidence inadmissible under Fed.R.Evid. 703. *Ealy v. Richardson-Merrell*, 897 F.2d 1159 (D.C. Cir. 1990).

APPENDIX C

UNITED STATES COURT OF APPEALS
For the Sixth Circuit

No. 90-5690

GARY TURPIN, *Plaintiff-Appellant*, BETTY TURPIN, Individually and as Parent and Natural Guardian of Brandy Turpin, a Minor, *Plaintiff*, v. MERRELL DOW PHARMACEUTICALS, INC., *Defendant-Appellee*.

March 11, 1992, Decided and Filed

Before: MERRITT, Chief Judge; KENNEDY and JONES, Circuit Judges:

MERRITT, Chief Judge. For a judicial system founded on the premise that justice and consistency are related ideas, the inconsistent results reached by courts and juries nationwide on the question of causation in Bendectin birth defect cases are of serious concern. In this Bendectin causation case, Judge Eugene Siler concluded that the evidence adduced on summary judgment was insufficient to allow a rational jury to find that Bendectin, a drug given to pregnant women to counteract the nausea of "morning sickness," caused the minor plaintiff's birth defects.

The general issue for review here is whether the trial judge erred by withdrawing the case from the jury and by granting summary judgment for the defendant pharmaceutical company. The more specific issues are, first, whether a court should judge for itself the validity of the reasoning process by which various competing qualified experts have reached their conclusions or should instead leave that question for the jury; and second, whether the evidence in this case, if so reviewed, is sufficient to withstand the defendant's motion for summary judgment.

We agree with Judge Siler that, although judges should respect scientific opinion and recognize their own limited

scientific knowledge, nevertheless courts have a duty to inspect the reasoning of qualified scientific experts to determine whether a case should go to the jury. Based on the record before us, we also agree with Judge Siler that whether Bendectin caused the minor plaintiff's birth defects is not known and is not capable of being proved to the requisite degree of legal probability based on the scientific evidence currently available. Taken in the light most favorable to the plaintiffs, the scientific evidence that provides the foundation for the expert opinion on causation in this case is not sufficient to allow a jury to find that it is more probable than not that Bendectin caused the minor plaintiff's injury. Therefore the case should not go to a jury.

We will first summarize the Bendectin causation issue and the case law that has developed during the past twelve years. We will then analyze the evidence in greater detail and show why it does not meet the legal test of causation.

I. *Overview*

The nausea of morning sickness affects many pregnant women and, although the causes are not completely understood, in extreme cases may cause permanent injury to the sufferer's unborn child. Merrell Dow manufactured and marketed Bendectin as an anti-nauseant prescription for morning sickness from 1956 until 1983 when it took the drug off the market despite continued approval from the Food and Drug Administration. Estimates indicate that Bendectin was prescribed from 1957 until 1982 to over 30 million women worldwide and to more than 17.5 million women in the United States. These women commonly took Bendectin during the first trimester of pregnancy.

Approximately seven weeks after becoming pregnant, Betty Turpin ingested Bendectin to combat morning sickness. The initial development of the fetus's fingers and toes occurs some four to eight weeks after conception. Seven months after Ms. Turpin first took the drug, her child, Brandy Turpin, the infant plaintiff in this case, was born with "limb reduction defects": severely deformed hands and feet, specifically fused joints and shortened or missing fingers and toes. Ms. Turpin took no other drugs during the course of her pregnancy, nor can her child's deformities be traced to any known genetic disorders.

Causation here is a matter of trying to measure probabilities. It requires a complex series of inferences drawn from scientific experiment and observation and statistical comparisons. For example, the plaintiffs rely primarily on animal experiments from which an inference is drawn that since chemical compounds in Bendectin, if administered at certain levels, cause birth defects in animals, they may cause similar defects in humans. The plaintiffs draw a further inference that Bendectin caused the birth defects in this particular case. These inferences are necessary because physicians who treated Brandy Turpin and other similarly situated children cannot diagnose the cause of these anomalies.

The defendant, too, reasons from the results of scientific studies to a particularized conclusion with respect to these plaintiffs. Merrell Dow relies primarily on statistical studies that purport to show that the incidence of certain birth defects is no higher with women who used Bendectin than with those who did not or, in the alternative, that where statistical associations indicating a possible causal relationship exist, they would not lead a reasonable expert to infer that Bendectin causes birth defects.

The causation proof in Bendectin birth defect cases is offered by expert witnesses who speak in terms of population groups and statistical samples rather than specific individuals. The expert witnesses on each side are often the same, from case to case, and even when different the scientific conclusions and theories are based on the same or similar statistical studies and scientific experiments. The cases are variations on a theme, somewhat like an orchestra which travels to different music halls, substituting musicians from time to time but playing essentially the same repertoire.

A brief survey of the reported Bendectin cases illustrates the inconsistency of courts that have dealt with the scientific problem of causation. We find only one reported case finally upholding a finding of causation. In *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100 (D.C. App. 1980), *aff'd in part on appeal after remand*, 563 A.2d 330 (D.C. App. 1989), *cert. denied*, 493 U.S. 1074 (1990), the appellate court reversed the

trial court's grant of a judgment n.o.v. and motion for new trial to the defendant and reinstated the jury's $750,000 verdict for the plaintiffs. On the other hand, in four other reported cases, juries returned verdicts for the defense which were allowed to stand. *Wilson v. Merrell Dow Pharmaceuticals*, 893 F.2d 1149 (10th Cir. 1990) (affirming judgment for the defendant and noting also that the plaintiffs' motion for judgment n.o.v. was correctly denied by the district judge); *Will v. Richardson--Merrell, Inc.*, 647 F. Supp. 544 (S.D. Ga. 1986) (denying plaintiffs' motion for judgment n.o.v.); *In re Richardson-Merrell, Inc. "Bendectin" Products Liability Litigation*, 624 F. Supp. 1212 (S.D. Ohio 1985), *aff'd*, 857 F.2d 290 (6th Cir. 1988) (denying plaintiffs' motion for judgment n.o.v. in an order addressing 818 of 844 consolidated multidistrict cases in the largest of all Bendectin cases); and *Cosgrove v. Merrell Dow Pharmaceuticals, Inc.*, 117 Idaho 470, 788 P.2d 1293 (1990) (affirming jury's finding that Bendectin was not the proximate cause of child's injuries).

Four federal circuits have held that plaintiffs failed as a matter of law to establish causation of birth defects. The Fifth Circuit, without ruling specifically on the admissibility of the plaintiffs' expert testimony, reversed a jury verdict for the plaintiffs and granted judgment n.o.v. to the defendant because adequate proof of causation was lacking. *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *reh'g. denied*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 110 S. Ct. 1511 (1990), *limited by Christopherson v. Allied-Signal Corp.*, 902 F.2d 362, 367 (5th Cir. 1990), *rev'd on reh'g on other grounds*, 939 F.2d 1106 (5th Cir. 1991)(en banc). Another circuit, the Ninth, affirmed a grant of summary judgment for the defendant after holding that the plaintiffs' reanalyses of Merrell Dow's epidemiological studies were unreliable for lack of peer review. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, No. 90-55397, 1991 U.S. App. LEXIS 29497 (9th Cir. Dec. 20, 1991). Two other circuits reached the same result by ruling inadmissible the plaintiffs' expert testimony on grounds that it was not the type "reasonably relied upon" by qualified experts in the specific fields of study. *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989) (reversing jury

verdict for the plaintiff; in the face of the defendant's epidemiological evidence, an insufficient foundation existed for the plaintiffs' animal and chemical studies); *Lynch v. Merrell-Nat'l Labs.*, 830 F.2d 1190 (1st Cir. 1987) (holding that the plaintiff's *in vivo* and *in vitro* studies were inadmissible; therefore, insufficient evidence existed to avoid summary judgment for the defendant); *see also Ealy v. Richardson-Merrell, Inc.*, 897 F.2d 1159 (D.C. Cir.), *cert. denied*, 111 S. Ct. 370 (1990) (reversing jury verdict for the plaintiff for $20 million in compensatory damages and punitive damages of $75 million, and granting judgment n.o.v. to the defendant after concluding that the plaintiff's evidence was inadmissible under *Richardson*), and *Ambrosini v. Richardson-Merrell, Inc.*, No. 86-278 (D.D.C. June 30, 1989)(relying on *Richardson* in granting judgment for the defendants).

Four District Court cases nationwide have granted summary judgment to the defendant for various reasons. *Lee v. Richardson-Merrell, Inc.*, No. 84-2228 (W.D. Tenn. Jan. 30, 1991) (relying on *Richardson*, *Brock*, and Judge Siler's opinion in this case); *Cadarian v. Merrell Dow Pharmaceuticals, Inc.*, 745 F. Supp. 409 (E.D. Mich. 1989) (holding that an inadequate foundation existed for expert's s opinion); *Hull v. Merrell Dow Pharmaceuticals, Inc.*, 700 F. Supp. 28 (S.D. Fla. 1988) (finding that the body of scientific literature established Bendectin's safety and that the infant plaintiff's mother took the drug too late in her pregnancy to affect the fetus); and *Monahan v. Merrell-Nat'l Labs.*, No. 83-3108-WD (D. Mass. Dec. 18, 1987)(finding that summary judgment for the defendant was required under the First Circuit's earlier holding in *Lynch*).

In contrast, other courts have either denied or reversed on appeal grants of summary judgment for the defendant in eight cases. In *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3rd Cir. 1990), the Third Circuit reversed the trial court's grant of summary judgment to Merrell Dow and remanded for the District Court to analyze the reasonableness of an expert witness's epidemiological opinion of causation under Federal Rule of Evidence 702. *See also Longmore v. Merrell Dow Pharmaceuticals, Inc.*, 737 F. Supp. 1117 (D. Idaho 1990)

(expressly declining to adopt *Richardson*, *Lynch*, and *Brock* approaches); *In re Bendectin Products Liability Litigation*, 732 F. Supp. 744 (E.D. Mich. 1990) (holding that collateral estoppel did not bar the plaintiffs on the issue of causation and that, in the face of experts' disagreements on necessity of epidemiological proof, the court could not reject other types of evidence); and *DePyper v. Navarro*, No. 116390 (Mich. Ct. App. May 9, 1991) (holding that the trial court erred under state law by not inquiring whether experts in field generally accepted the methodology of the plaintiffs' expert). For other denials of summary judgment or denials of the defendant's motions for directed verdict, see *Hagen v. Richardson-Merrell, Inc.*, 697 F. Supp. 334 (N.D. Ill. 1988) (denying summary judgment on causation but granting summary judgment on punitive damages); *Mangels v. Richardson-Merrell, Inc.*, No. R-83-3272 (D. Md. Aug. 17, 1987) (summary judgment denied because a triable issue of fact existed for jury resolution); and *Lanzilotti v. Merrell Dow Pharmaceuticals, Inc.*, No. 82--0183 (E.D. Pa. July 10, 1086) (denying the defendant's motion for a directed verdict).

The fundamental reasons for the inconsistency of the legal system in handling Bendectin claims appear to be first, the difficulty of scientists and hence of judges, lawyers and jurors in knowing what reasonable inferences of causation to draw from animal experiments and epidemiological studies; and second, the uncertainty of judges about how far they should enter the scientific thicket of conflicting inferences in order to determine whether the basis of a scientific opinion concerning causation is sufficiently plausible to allow a jury to ground a verdict on it. There are two important questions here: How hard should judges look at the reasonableness of scientific theories and inferences before they decide whether there is enough to the case for it to go to the jury? If we apply a "hard look" doctrine, as we are inclined to do in scientific cases based primarily on expert testimony, what exactly are the general scientific experiments and studies capable of showing about whether Bendectin causes birth defects in a particular case?

We believe that close judicial analysis of such technical and specialized matter is necessary not only because of the likelihood

of juror misunderstanding, but also because expert witnesses are not necessarily always unbiased scientists. They are paid by one side for their testimony. Although there is no suggestion of unethical scientific conduct in the present case, the potential for exaggeration and fraud on the court is present and may be impossible to discover without close inspection and careful consideration of the record. As Judge Leventhal observed in the context of administrative law, in some circumstances there exists a "combination of danger signals" requiring enhanced "judicial vigilance to enforce the Rule of Law." *Greater Boston Television Corp. v. F.C.C.*, 444 F. 2d 841, 851-52 (D.C. Cir. 1970). In such situations, "a court does not depart from its proper function when it undertakes a study of the record, hopefully perceptive, even as to evidence on technical and specialized matters . . . ." *Id.* at 850. We find that this case presents a scenario justifying the type of judicial review recommended by Judge Leventhal.

II.

In this legal context, we review the evidence and arguments offered by the parties on summary judgment. In determining and applying the correct standards of proof on summary judgment in scientific cases, we look to the rules of sufficiency of the evidence to decide whether juries should be allowed to hear the evidence as well as the rules of admissibility of expert testimony that shape the facts and opinions to be considered. This case, we believe, should be decided on the rules of the sufficiency of evidence of causation on summary judgment, as Judge Siler held below in the alternative.

In the instant case, the plaintiffs claim that their infant daughter's birth defects were caused by the mother's use of Bendectin during her pregnancy and specifically by one ingredient, doxylamine succinate. The plaintiffs' case relies on animal studies and attacks the defendant's epidemiological studies. The defendant's case relies on the epidemiological studies and attacks the animal studies.

The plaintiffs offered expert opinions from ten witnesses in eight scientific fields to assess whether Bendectin is "teratogenic," *i.e.*, capable of causing birth defects. These opinions

were based on *in vitro* and *in vivo* animal studies, and reassessment of the defendant's epidemiological studies derived from study of humans. In support of its motion for summary judgment, the defendant relies primarily on 35 human epidemiological studies supporting a finding that the use of Bendectin does not cause birth defects. Some of these studies were conducted by scientists under contract with the defendant. Others were independent.

A. *Defendant's Proof -- Epidemiological Studies*

Both sides appear to accept the fact that limb defects generally appear in less than one in 1,000 live births. The defendant's proof consists in large measure of the 35 extant studies published in medical and scientific journals on the statistical relationship between the use of Bendectin and the incidence of various forms of birth defects in babies, none of which conclude that a causal connection exists. For an extended explanation of the complex statistical methodology used in such epidemiology studies, including the use of such terms of art as the "null hypothesis," "significance testing," "P value," "relative risk" and "confidence interval," see Part 1.B of the Third Circuit's recent Bendectin opinion, *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 945-49 (3rd Cir. 1990).[6]

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[6] Several statistical terms of art are essential to an understanding of the meaning of these epidemiological studies. The risk of injuries from a suspected cause is expressed as *relative risk*. To calculate relative risk, the number of occurrences of a given birth defect in an exposed group is divided by the number of occurrences in the control, or unaffected group. If the given defect occurs with equal frequency between the exposed and control groups, the relative risk would be 1.0. A relative risk of 1.0 is considered inconclusive, in that a researcher cannot state that a suspected agent does or does not cause a defect (i.e., the "null hypothesis" or "no association"). *See generally* Allen Mitchell *et al.*, *Adverse Drug Effects and Drug Surveillance, in Pediatric Pharmacology* 68-69 (Sumner Yaffe ed. 1980). A relative risk of less than 1.0 suggests that a suspected agent does not cause a birth defect. A relative risk greater than 1.0 suggests that the substance may cause a given birth defect.

To gauge the reliability and credibility of their reports when repeated

randomly, statisticians use a device known as the *confidence interval*. The confidence interval is not a "burden of proof" in the legal sense; rather, it is a common sense mechanism upon which statisticians rely to confirm their findings and to lend persuasive power within their profession. The confidence interval has two components: a percentage, and an interval or range. The *percentage* part is established by the statistician in advance of performing the studies. Frequently this percentage is set at 95 percent, although that value is somewhat arbitrary and 85 to 90 percent figures are also used. The *interval*, on the other hand, represents a range of possible values at high and low ends of a scale of relative risk. *See, e.g.*, Kenneth Rothman, *Modern Epidemiology* 119 (1986). At a 95 percent interval the true relative risk value will be between the high and low ends of the confidence interval 95 percent of the time. *See* Neil Cohen, *Confidence in Probability: Burdens of Persuasion in a World of Imperfect Knowledge*, 60 N.Y.U. L.Rev. 385, 398-400 (1985) [hereinafter *Confidence in Probability*], for example of confidence intervals and their use.

To better understand confidence intervals, it may be helpful to picture a line, marked at hundredths intervals and extending from zero to infinity. The marking at 1.0 represents a relative risk of 1.0, the "null value." If a confidence interval of "95 percent between 0.8 and 3.10" is cited, this means that random repetition of the study should produce, 95 percent of the time, a relative risk somewhere between 0.8 and 3.10. Because this confidence interval includes relative risk values both less than and exceeding 1.0, the null value, a researcher cannot state that the results are statistically significant. David Kaye, *Is Proof of Statistical Significance Relevant?*, 61 Wash. L.Rev. 1333, 1343-44 (1986), *cited in DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 948 (3rd Cir. 1990). For an example of such a study, see Jose Cordero *et al.*, *Is Bendectin a Teratogen?*, 245 JAMA 2307 (1981), cited *infra*. Similarly, it is possible that a range may be entirely below 1.0, meaning that the agent does not cause birth defects. If, however, the confidence interval spans a range entirely above 1.0 -- *e.g.*, from 1.75 to 10.75 -- then this interval would be statistically significant and would show a greater likelihood that the suspected agent did cause the studied defect. For an example of such an interval, see Brenda Eskenazi & Michael Bracken, *Bendectin (Debendox) As a Risk Factor for Pyloric Stenosis*, 144 Am.J.Obstetrics & Gynecology 919 (1982), cited *infra*.

The sample size for any study also has an effect, both on the confidence interval and the "power" of the study. *Power* is the study's probability of detecting a difference in outcomes between exposed and non-exposed groups. *See* Office of Technology Assessment, Report No.

The following examples illustrate the nature and findings of these 35 studies, with six studies representative of the group:

1. ***The San Francisco Study*****:** Two University of California researchers studied effects of six anti-nauseant drugs on 11,481 pregnancies in the San Francisco area over seven years. Bendectin was prescribed in only 628 of these cases. Birth defects were monitored at three ages: one month, one year, and five years (though limb defects in particular were not isolated and reported). The average rate of all types of birth defects for Bendectin cases at the age of one month was 0.8 in every 100 births. This average rate is less than the average rate of the birth defects found in mothers who did not use Bendectin. The comparative rates at the one and five-year periods were similar. Although no specific relative risk was assigned to Bendectin use, the authors concluded that Bendectin, when taken at a recommended dosage level, was not teratogenic. Lucille Milkovich & Bea Van den Berg, *An Evaluation of the Teratogenicity of Certain Antinauseant Drugs*, 125 Am.J.Obstetrics & Gynecology 244, 245-48 (1976).

2. ***The Boston and Harvard Study*****:** Six doctors from Boston University and the Harvard School of Public Health evaluated a

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OTA-BA-266, *Reproductive Health Hazards in the Workplace* 166 (1985). The higher the study's power, the stronger are its conclusions and findings regarding its outcome. If a sample population is small, however, the power of the study will likely be less. The information behind the study is less, and the confidence interval will likely span a wider range for a smaller sample group than for a larger one. The power is less for the smaller group than for the larger group, even though the confidence interval may still be set at 95 percent, because the smaller study's predictive value is lessened by a wide confidence interval range. A statistician could accordingly describe the probability of choosing an expected outcome in the large study as being greater than in the smaller study. Cohen, *Confidence in Probability*, at 398-99.

As can be seen, in may aspects, the concepts of confidence intervals, sampling sizes, population and power are mutually interdependent. For an overview of how epidemiology is used in risk assessment, see Proposed Guidelines for Assessing Female Reproductive Risk, 53 Fed.Reg. 24,834, 24,840-41 (1988).

group study of 50,282 mothers and children for Bendectin's possible effect on birth defects. Of these mothers, 1,169 took Bendectin during their first four months of pregnancy, with 79 births resulting in various birth defects. Limb defects were not specifically reported. The 49,113 mothers who were not exposed to Bendectin gave birth to 3,169 infants who had various birth defects. Overall, 4.7 percent of those mothers exposed to Bendectin gave birth to deformed infants, while 4.5 percent of non-exposed mothers did. Thus, the relative risk of birth defects for Bendectin use was 1.07 at a 95 percent confidence level. The confidence interval was not listed. Taking this into account, the authors concluded that no "statistically significant" association existed, providing no evidence that Bendectin's components -- including doxylamine succinate -- were harmful to the fetus. Samuel Shapiro *et al.*, *Antenatal Exposure to Doxylamine Succinate and Dicyclomine Hydrochloride (Bendectin) in Relation to Congenital Malformations, Perinatal Mortality Rate, Birth Weight, and Intelligence Quotient Score*, 128 Am.J.Obstetrics & Gynecology. 480, 481-84 (1977).

3. *The Atlanta Study*: Over 280,000 births were monitored in the Atlanta area over a ten-year period for maternal exposure to various drugs including Bendectin. This population base was twenty times larger than that in the San Francisco study. Of 1,231 birth defects cases, 117, or 9.5 percent, of the mothers took Bendectin. Of 129 children born with limb defects, 14 (10.9 percent) had mothers who took Bendectin. The study calculated a relative risk of 1.18 at a 95 percent confidence interval between 0.65 and 2.13. However, for one subgroup of limb defects known as the "amniotic band complex," a higher relative risk -- 3.88 -- was reported. Therefore, the risk of a Bendectin-exposed mother giving birth to a child with this specific condition was almost four times greater than that which would occur in a population of non-exposed mothers. Two other forms of birth defects (herniated-brain and esophageal defects) had relative risks of 1.84 and 2.47, with 95 percent confidence levels between 0.63 and 5.37 and between 0.84 and 4.89, respectively.

For most birth defects, including limb defects, the authors determined that no "statistically significant" associations could be traced. As for the three above-mentioned possible associations, the authors noted possible confounding factors that might weaken the power of such associations, so that "the data [did] not suggest that Bendectin is causally associated" with birth defects. Jose Cordero *et al.*, *Is Bendectin a Teratogen?*, 245 JAMA 2307 (1981).

4. *Pyloric Value Defects*: The highest associations found between Bendectin use and birth defects were focused not on limb defects but on pyloric stenosis (abnormal constriction of the stomach's pyloric valve). In one Yale School of Medicine study, a relative risk of 1.40 was detected between mothers using Bendectin (1,427 cases) and non-users (3,001) for birth deformities. When the survey exclusively focused on infants with pyloric valve defects, six mothers taking Bendectin gave birth to children with this defect, as opposed to 29 mothers who did not use the drug. At a 95 percent confidence interval between 1.75 and 10.75, the relative risk of this stomach valve defect was 4.33. "Thus, more than one in 10 cases of pyloric stenosis may be due to maternal use of Bendectin," although no direct causal relationship could be ascertained. Brenda Eskenazi & Michael Bracken, *Bendectin (Debendox) As a Risk Factor for Pyloric Stenosis*, 144 Am.J.Obstetrics & Gynecology 919, 921-24 (1982). The same study noted that one child with a limb reduction defect was born to a mother taking Bendectin, while five defects occurred in children of women not taking the drug. Although a relative risk of 4.19 resulted for limb defects, this was regarded as "nonsignificant" by Eskenazi and Bracken, *id.* at 923, possibly due to the smallness of the group studied and the wide range of the confidence interval.

A later study conducted by Boston University Medical Center of 13,346 births around Puget Sound tended to support Eskenazi's and Bracken's findings. In 3,385 cases involving Bendectin use, 13 babies were born with pyloric valve defects, while 13 women out of 9,511 not exposed to the drug gave birth to affected children. These findings yielded a 2.5 relative risk ratio at a 95 percent confidence interval between 1.2 and 5.2. Despite

this positive association, however, the Boston University researchers noted "the absence of any apparent biologic basis" to support the connection between Bendectin use and development of purely internal deformities like pyloric stenosis. The researchers also acknowledged that severity of the mothers' nausea could have confounded the results. Pamela Aselton *et al.*, *Pyloric Stenosis and Maternal Bendectin Exposure*, 120 Am.J.Epidemiology 251, 252-56 (1984). An earlier study by two members of the same group focused on limb disorders in the same geographic region. Of 5,255 women studied, two infants out of 1,364 born to women who used the drug had limb defects, while four infants in the 3,841 Bendectin-free mothers had defects. The study yielded a relative risk of 1.4 and a 95 percent confidence interval between 0.26 and 7.71. A related study disclosed that of 2,255 infants born to Bendectin users, two children were born with malformed limbs, compared with six similar limb defects in babies born to 4,582 non-users. From this, a relative risk of 0.9 at a 95 percent confidence level between 0.29 and 2.98 was derived. The researchers concluded this was "evidence against a strong association." Pamela Aselton & Herschel Jick, *Additional Follow-Up of Congenital Limb Disorders in Relation to Bendectin Use*, 250 JAMA 33 (1983).

5. *The Sydney Study*: University of Sydney researchers compared pregnancy histories for mothers of 155 children born with limb reduction defects with those for the mothers of 274 control group children; 26 percent of the 429 mothers in both groups used Bendectin during the first trimester of pregnancy. The relative risk resulting was 1.1, with a 95 percent confidence interval between 0.8 and 1.5. The Australian researchers concluded that "[o]n these figures, there is no evidence that women who take [Bendectin] . . . are more likely to bear a limb-deficient child than women who do not take this drug." Janet McCredie *et al.*, *The Innocent Bystander*, 140 Med.J.Austl. 525, 526-27 (1984).

6. *The National Institute of Health Study*: In the most recent Bendectin study, two National Institute of Health researchers evaluated 31,564 births in Northern California. Of those women 2,771 (nine percent) had used Bendectin. For 58 categories of

defects studied -- limb defects, however, were not specifically monitored -- 135 defects occurred in cases of Bendectin exposure, while 1,439 defects occurred in non-exposed cases. Relative risks were greatest in three categories: lung defects (4.6), microcephaly, *i.e.*, small head size (3.1), and cataracts (3.7). The 95 percent confidence intervals varied widely for these three categories, ranging between 1.9 to 10.9 for lung defects, 1.8 to 15.6 for microcephaly, and 1.2 to 24.3 for cataracts.

Despite these findings, the authors surmised that the three statistically significant defect groups were possibly spurious, as they were "exactly the number . . . that would have been expected by chance." How this determination was made, however, is not specified by the authors. The authors concluded that no increase in overall rates of defects existed after Bendectin use and that the three associations "are unlikely to be causal." Patricia Shiono & Mark Klebanoff, *Bendectin and Human Congenital Malformations*, 40 Teratology 151, 152-55 (1989).

In addition to the 35 epidemiological studies, the defendant also offers as evidence the fact that no one has detected a decrease in the incidence of birth defects after Bendectin was removed from the market in 1983. Dr. Lamm so testified for the defendant based on a number of studies.

B. *Plaintiffs' Challenge to the Epidemiological Proof*

The plaintiffs claim that the defendant's 35 studies are based on samples which are too small to prove the absence of causation in light of the infrequency of instances of birth defects in general; that they do not adequately isolate limb reduction defects from other birth defects; that they do not control for many confounding factors such as smoking and the use of other drugs; that they impose a much higher level of scientific certainty of association (95 percent) than required by the preponderance of

the evidence standard of proof (*i.e.*, 51 percent);[7] and that some of the studies can be read to show some statistically significant association if a much lower level of certainty is used. In essence the plaintiffs argue that the 35 statistical studies do not prove or disprove anything concerning the relationship between Bendectin and limb reduction defects.

At least two expert witnesses for the plaintiffs attack the persuasive force of the defendant's statistical comparisons of the incidence of Bendectin-related birth defects. Dr. Glasser criticized the defendant's use of studies by Aselton, Jick, Cordero and Eskenazi as not correctly considering other birth defects, such as heart and pyloric valve defects or cleft palates, in assessing Bendectin's capacity for limb birth defects. In his affidavit, Dr. Glasser also criticized the Cordero, Eskenazi and McCredie studies for incorrectly inferring that no association existed between Bendectin use and infant limb reduction. Dr. Swan, similarly, rejected these studies' sole reliance on a relative risk of 1.0 within a 95 percent confidence interval as a basis for concluding that Bendectin does not cause birth defects in humans. Dr. Swan further claimed that several of the studies were conducted using insufficient populations or control groups, so that scientists wrongly calculated exposures to the drug. Dr. Swan viewed these and other factors as confounding the validity and power of such reports; however, both Drs. Glasser and Swan relied on these studies as the basis for their own recalculations, using a lower confidence interval that is claimed to derive a higher relative risk. Both experts concluded from their own reassessments that to a reasonable degree of epidemiological certainty, there is some association between Bendectin and limb reduction defects.

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[7] While scientists' use of confidence intervals is as a common-sense device to give professional weight to their results, such confidence intervals are not the same as the preponderance of the evidence standard of proof. This requires proving one's case by the greater weight of the evidence. Where the weight is equally divided between the plaintiff and the defendant, the party bearing the burden of proof must lose. Reduced to a percentage, this requires proof of one's case to at least 51 percent of the evidence.

Although we agree with the defendant that its epidemiological studies and Dr. Lamm's testimony constitute evidence on which a jury might ground a defendant's verdict, we agree with the plaintiffs' experts that this evidence is by no means conclusive. The defendant's claim overstates the persuasive power of these statistical studies. An analysis of this evidence demonstrates that it is possible that Bendectin causes birth defects even though these studies do not detect a significant association.

Limb reduction defects occur in such a small percentage of both Bendectin and non-Bendectin live births -- as noted, these occur in less than one in every 1,000 -- that it would take a carefully controlled comparison of a very large number of births to instill confidence in the predictive power of the outcome. Also, many of the defendant's studies apparently do not control for many factors that may be crucial for scientists to accord great weight to the studies, such as the stage of pregnancy during which the mother took Bendectin, the other drugs the mother may have taken, or other harmful conditions, natural or otherwise, that may have been part of the mother's environment.

The Bendectin epidemiological studies are examples of a large number of studies of birth defects that demonstrate significant scientific uncertainty concerning their causes. A recent epidemiological study observes that "the etiology of congenital anomalies is poorly understood, with an estimated 60 [percent] of all human birth defects having no known cause." Patricia Olshan *et al.*, *Paternal Occupation and Congenital Anomalies in Offspring*, 20 Am.J.of Indus.Med. 447 (1991) (exploratory study finding a correlation between birth defects and the occupation of the father, but reasons for result yet unknown). The science of epidemiology is currently unable to identify the causes of many birth defects or to exclude from consideration many possible causes, including Bendectin and a host of other outside agents and environmental factors.

C. *Plaintiff's Proof -- Animal Studies*

The cartilage cells that later become the bones of fingers and toes begin to form in the human embryo during the fourth through eighth weeks of pregnancy. The plaintiffs' theory is that

chemical compounds in Bendectin interfere with the formation of these cartilage cells, or chondrogenesis, and that this causal relationship is shown by animal experiments. The plaintiffs' proof includes experiments with animal cells and embryos, known as *in vitro* studies, performed by developmental biologists to observe possible toxic effects on animal tissue when tested in petri dishes. Other animal experiments, *in vivo* studies, consisted of tests performed on animals such as rabbits, chickens, monkeys, rats and dogs to determine if Bendectin's ingredients created birth defects at various dosage levels. In these experiments, doxylamine succinate, an ingredient of Bendectin, was injected into animal cells that produce or grow into cartilage that becomes the bones in which limb defects may occur. The plaintiffs' scientific hypothesis based on these studies is this: Because doxylamine succinate interferes with cartilage cell formation in animal cells and test animals, Bendectin is "capable" of causing similar limb defects in humans. The following examples illustrate the nature and findings of these animal cell studies:

1. *In vitro studies*: As a developmental biologist, Dr. Newman stated that he performs experiments on embryonic cells in petri dishes to determine how those cells develop and create tissue. Due to their similarities to the human embryo, chicken and mice or rat embryos are most frequently used in these studies. Limb-forming cells are removed from the embryo -- for chickens, wing and leg formation cells are used -- and are isolated in a dish, where selected cells are treated with a suspected teratogen. Changes in cell differentiation between the control group of untreated cells and the exposed group are observed and recorded.

Dr. Newman pointed to experiments on rat cells with substances similar to doxylamine succinate. In these *in vitro* tests, various defects including limb reduction were observed. Other *in vitro* tests performed by National Institute of Health experts and relied upon by Dr. Newman found that doxylamine succinate interfered with cartilage development in mice and chicken limb cells. In one experiment, the addition of 10 micrograms of Bendectin to an animal cell culture reduced one

of the components of cartilage cells, proteoglycan, by 30 percent. Similarly, 50 micrograms of Bendectin per milliliter of a culture reduced proteoglycan production by 50 percent, thus suggesting a strong teratogenic effect in the animal cells tested.

Like the other scientists who testify concerning animal experiments, Dr. Newman can only testify that these chemical compounds connected with Bendectin are "capable of causing" limb defects in humans, not that they do cause such defects.[8]

2. ***In vivo studies***: Dr. Gross, a pathologist and veterinary medical expert with the Environmental Protection Agency, described the nature of the *in vivo* studies proffered by the plaintiffs. In these experiments, suspected teratogens are administered to pregnant female animals. Shortly before their birth, the infants are removed from the mother and studied for defects. Dr. Gross examined a variety of these studies, including Bendectin experiments performed by the defendant on rats and rabbits. In one such study, doxylamine succinate was given daily to female rabbits at three varying dosage levels. No defects were observed at the two lower levels; however, 40 percent of the litters born to females at the highest dosage had some congenital defects observed. As dosages were increased even higher, "outright death" of animal infants occurred. Dr. Gross rejected several of Merrell Dow's other studies as being confounded by the presence of defects in the non-exposed control group while other studies indicated defects that were assessed by Dr. Gross as being compatible with teratogenicity, although not all of the

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[8] As stated in his affidavit: "It is my opinion . . . specifically with respect to my experience with limb development and knowledge of the impact of the antihistamine Bendectin on cell function, that Bendectin is capable of interfering with the development of the limb in the human being and causing birth defects in the developing limb . . . and that Bendectin is a human teratogen." Dr. Newman states further that, although he is not a medical doctor, his review of the medical files of Brandy Turpin and her mother indicates the infant plaintiff's defects are "consistent with the effects of teratogen," with Bendectin being "capable" of being such a teratogen. Aff., Dr. Newman, *Turpin v. Merrell Dow*, No. 84-105 (E.D. Ky. Mar. 27, 1990), at 8, 10.

observed defects were limb-related. Dr. Gross stated that testing animals at levels higher than human dosages and then extrapolating the results to humans was a generally accepted practice. Based on his review of the studies, Dr. Gross gave his opinion that doxylamine succinate in Bendectin has the "capacity" to interfere with human cell development at normal dosages but could not testify that it does cause such defects.

A recognized text on teratology states the customary scientific view that "it has become axiomatic in experimental teratology that agents capable of causing any adverse biological effects can usually also be shown to be embryotoxic under the right conditions of dosage, developmental stage, and species susceptibility," and that "virtually all drugs and a great range of chemicals can indeed be shown to be embryotoxic under appropriate laboratory conditions." James Wilson, *Current Status of Teratology*, in *Handbook of Teratology* 60 (J. Wilson & C. Fraser, eds. 1977). The author concludes that to "eliminate drugs and chemicals because they can be shown to be embryotoxic at high dosage would be unacceptable" because to do so "would eliminate most drugs and many useful chemicals upon which modern society depends heavily." *Id.*

The weakness of the plaintiffs' case results from the care with which reputable scientists use animal experiments to predict causation in humans. This weakness arises from the fact that different species of animals react differently to the same stimuli for reasons not entirely understood.[9] Immune systems, nervous

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[9] Several animal studies of cortisone, for example, found that it causes severe cleft palate birth defects in several animal species, but it does not cause this effect in humans. Alfred Bongiovanni & Arthur McPadden, *Steroids During Pregnancy and Possible Fetal Consequences*, 11 Fertility & Sterility 181, 184-45 (1960) ("With doses more closely resembling those employed in medical practice," doses of cortisone led to frequent cleft palate defects in several species, especially mice, while surveys of human pregnancies demonstrated that almost none of this defect could be attributed to cortisone treatments. "It would appear, therefore, that in spite of the awesome results reported in other species, the human fetus is rarely injured by maternal treatment with corticoids."). *See also* Beverley Murphy &

systems, and metabolisms (*i.e.*, physical processing of chemical compounds) may differ greatly between species. No doubt there may be other animal experiments which, to cite one example, because of the extreme toxicity of the substance tested, would permit a reasonable jury to find that it is more probable than not that the substance causes a similar harm to humans. But Bendectin is not such a case.

The decisive weakness in the plaintiffs' animal studies is that the factual and theoretical bases articulated for the scientific opinions stated will not support a finding that Bendectin more probably than not caused the birth defect here. On summary judgment, under the doctrine of *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986), and *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986), the expert evidence must show the elements required for a finding of causation. Here, except for Dr. Palmer's testimony discussed below, the plaintiffs' experts stop short of testifying that Bendectin more probably than not caused the birth defects in babies. They stop short because they have no factual or theoretical basis for a stronger hypothesis. They testify that the animal studies show that Bendectin is "capable of causing," "could cause" or its effects are "consistent with causing" birth defects, not that it probably causes birth defects in general or that it did in this case. In short, they testify to a possibility rather than a probability.

Dr. Palmer, a medical doctor, is the only witness who testified in his affidavit that Bendectin caused Brandy Turpin's defects. He stated:

> It is my opinion . . . that [animal *in vivo* and *in vitro* studies, and epidemiological and other human data] shows that Bendectin and specifically its component,

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Charlotte Branchard, *Fetal Metabolism of Cortisol*, 5 Current Topics in Experimental Endocrinology 197, 221 (1983) (injections of cortisone will precipitate labor in pregnant sheep, cows, goats, rabbits, and rats; this does not occur in humans), and Elwyn Grimes, Jamil Fayez & Gerald Miller, *Cushing's Syndrome and Pregnancy*, 42 Obstetrics & Gynecology 550, 558 (1973) (accepting findings of the Bongiovanni and McPadden report).

> doxylamine succinate, has teratogenic properties . . . . I have also examined the medical records pertaining to Brandy Turpin and it is my opinion . . . . that Bendectin did cause the limb defects from which she suffers.

We cannot find, however, that this testimony is anything more than a personal belief or opinion. The grounds for his opinion are subject to the same criticism as the animal studies and epidemiological reanalyses submitted by the plaintiffs' other experts: the evidence cited in support of his conclusion is insufficient to meet the plaintiffs' burden of proof. Dr. Palmer does not testify on the basis of the collective view of his scientific discipline, nor does he take issue with his peers and explain the grounds for his differences. Indeed, no understandable scientific basis is stated. Personal opinion, not science, is testifying here. Dr. Palmer's own expressed skepticism as to the value of extrapolating human conclusions from animal studies further confounds the issue. Upon analysis, we conclude that Dr. Palmer's conclusions go far beyond the known facts that form the premise for the conclusion stated. This conclusion so overstates its predicate that we hold that it cannot legitimately form the basis for a jury verdict. Beyond that Dr. Palmer's opinion testimony, to the extent that it is personal opinion as described above, is inadmissible. Fed.R.Evid. 703; *see also Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 423-24 (5th Cir. 1987) (physician's unsupported personal opinion of causation held inadmissible), and *Calhoun v. Honda Motor Co.*, 738 F.2d 126, 131-32 (6th Cir. 1984) (expert testimony must be based on the evidence, so as to be removed from the realm of guesswork and speculation).

We do not mean to intimate that animal studies lack scientific merit or power when it comes to predicting outcomes in humans. Animal studies often comprise the backbone of evidence indicating biological hazards, and their legal value has been recognized by federal courts and agencies. *See, e.g., International Union, UAW v. Johnson Controls, Inc.*, 111 S. Ct. 1196, 1215 (White J., concurring) (*citing Industrial Union Dep't v. American Petroleum Institute*, 448 U.S. 607, 657 n.64 (1980)); *Environmental Defense Fund, Inc. v. EPA*, 548 F.2d 998, 1006-07 (D.C. Cir.

1976); Proposed Guidelines for Assessing Female Reproductive Risk, 53 Fed.Reg. 24,834, 24,836-39 (1988) (discussing the use of animal studies to identify and assess reproductive hazards for human females); Proposed Guidelines for Assessing Male Reproductive Risk, 53 Fed.Reg. 24,850, 24,853-60 (1988) (discussing the use of animal studies to identify and assess reproductive hazards for human males).

Here, the record's explanation of the animal studies is simply inadequate. Although the animal studies themselves may have been scientifically performed, the exact nature of these tests is explained only in general terms. The record fails to make clear why the varying doses of Bendectin or doxylamine succinate given to the rats, rabbits and *in vitro* animal cells would permit a jury to conclude that Bendectin more probably than not causes limb defects in children born to mothers who ingested the drug at prescribed doses during pregnancy. The analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue of human birth defects is too wide. Under such circumstances, a jury should not be asked to speculate on the issue of causation.

Accordingly, the judgment of the District Court is **AFFIRMED**.

APPENDIX D

UNITED STATES COURT OF APPEALS
For the District of Columbia Circuit

No. 90-7146 and No. 90-7148

TERESA AMBROSINI, et al.,

Appellants,

v.

JORGE LABARRAQUE, M.D., et al.,

Appellees.

Appeal from the United States District Court
For the District of Columbia

(June 12, 1992)

Before: MIKVA, *Chief Judge*, RUTH B. GINSBURG and RANDOLPH, *Circuit Judges*.

Opinion for the Court filed by *Chief Judge* MIKVA.

MIKVA, *Chief Judge*: Escolastica and Bruno Ambrosini, on behalf of themselves and their daughter Teresa, appeal a decision by the district court granting summary judgment in favor of defendants, The Upjohn Company and Dr. Jorge Labarraque. The district court held that the Ambrosinis failed to present specific, admissible scientific evidence sufficient to create a genuine issue of material fact on the issue whether the drug Depo-Provera caused the birth defects suffered by Teresa Ambrosini. The Ambrosinis argue that the district court erred in applying this court's earlier decision in *Richardson v. Richard-*

son-Merrell, Inc., 857 F.2d 823 (D.C. Cir. 1988), as well as Federal Rule of Evidence 703, in excluding their experts' affidavits. The Ambrosinis contend that the affidavits had a sufficient foundation under Rule 703 and contained the detail necessary to defeat the motion for summary judgment. Because we are convinced that the district court erred in applying the *Richardson* decision, as well as the standards governing summary judgment, we reverse the district court's grant of summary judgment as premature and remand for further proceedings.

I. BACKGROUND

Teresa Ambrosini suffers from severe birth defects including facial and ear malformations, hearing loss due to middle ear abnormalities, eye and vertebral malformations, and cleft lip and palate. The Ambrosinis brought an action against the manufacturers of the drugs Bendectin and Depo-Provera claiming that the drugs, either individually or in combination, caused Teresa's birth defects. The Ambrosinis also named as a defendant Mrs. Ambrosini's doctor, Dr. Jorge Labarraque, who prescribed the drugs. The claims against the manufacturer of Bendectin were later dismissed leaving only Upjohn, the manufacturer of Depo-Provera, and Dr. Labarraque as defendants.

After preliminary discovery, Upjohn moved for summary judgment, contending that no reliable scientific evidence exists to support the contention that Depo-Provera caused Teresa's birth defects. In support of its motion, Upjohn submitted the affidavit of Dr. Joe Leigh Simpson who discussed three epidemiological studies, as well as other published articles and studies, all indicating that medroxyprogesterone (the chemical name for Depo-Provera) did not cause the type of birth defects suffered by Teresa Ambrosini.

In response to Upjohn's motion, the Ambrosinis submitted the affidavits of two expert physicians, Dr. Allen S. Goldman and Dr. Brian Strom. At the same time, the Ambrosinis moved to amend their list of experts provided under Federal Rule of Civil Procedure 26(b)(4) by replacing their previously named experts

with Dr. Goldman and Dr. Strom. Although Upjohn opposed the switch, the district court did not rule on the Ambrosinis' motion and considered the experts' affidavits for the purpose of ruling on the summary judgment motion.

In his affidavit, Dr. Goldman stated, in relevant part, that:

> I am familiar with the available scientific and epidemiological data concerning progestin and progesterone agents including the product manufactured by the defendant Upjohn Company known as Depo-Provera, and it is my opinion within a reasonable degree of medical and scientific certainty that Depo-Provera does cause severe and disfiguring birth defects of the type that is suffered by Teresa Ambrosini. It is further my opinion that within a reasonable degree of medical certainty Teresa Ambrosini's birth defects were a result of the ingestion of Depo-Provera.

Dr. Goldman's affidavit did not, however, explain in detail the basis for his conclusion nor did it specifically state which studies, reports, or articles he relied on.

Dr. Strom stated in his affidavit that:

> It is my opinion that from a review of the epidemiological data that progestins, in general, do cause birth defects. This opinion is based upon the epidemiological data that is available in the literature. Further, in utilizing my education, training, and experience in the field I have used the same methodology that is generally and reasonably relied upon by epidemiologists and specifically those epidemiologists who interpret data involving drugs that are believed to cause birth defects.

Dr. Strom's affidavit also did not identify the publications, studies, or methodology he used in forming his opinion.

After considering the affidavits submitted by both parties, the district court granted Upjohn's motion for summary judgment. The court reasoned that "plaintiffs have failed to demonstrate that there are genuine issues of material fact or to identify admissible

scientific evidence upon which a jury could find that Depo-Provera is a human teratogen." *Ambrosini v. Richardson-Merrell, Inc., et al.*, No. 84-3483, slip op. at 13 (August 31, 1990) (hereinafter *Memorandum Opinion*). The court interpreted our decision in *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S.Ct. 218 (1989) as requiring "specific, admissible scientific proof" in support of a claim that a drug is responsible for causing birth defects. *Memorandum Opinion*, at 8. The court held that the "conclusory and unsupported" affidavits submitted by the experts were insufficient under *Richardson*, as well as under Rule 56 of the Federal Rules of Civil Procedure, to defeat Upjohn's motion for summary judgment. *Memorandum Opinion*, at 12.

II. ANALYSIS

A. *Expert Opinion Under* Richardson.

We first address the district court's conclusion that summary judgment was proper under our decision in *Richardson*. *Richardson* addressed the admissibility of expert testimony under Federal Rule of Evidence 703 which governs the basis for expert opinions. The Rule provides:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

Fed. R. Evid. 703. Sometimes referred to as an "expert testimony exception to the hearsay rule," *see e.g. United States v. Unruh*, 855 F.2d 1363, 1376 (9th Cir. 1987), Rule 703 broadens the acceptable bases for expert testimony by allowing an expert to base an opinion on hearsay and other evidence not admissible in court. *See* Fed. R. Evid. 703 advisory committee's note; JACK B. WEINSTEIN & MARGARET A. BERGER, WEINSTEIN'S EVIDENCE ¶ 703[01], at 6-7 (1991). Also, the Rule allows an expert to avoid the time consuming process of introducing

otherwise admissible evidence that forms the basis for the expert's opinion. As the advisory committee recognized:

> [A] physician in his own practice bases his diagnosis on information from numerous sources and of considerable variety, including statements by patients and relatives, reports and opinions from nurses, technicians and other doctors, hospital records, and X rays. Most of them are admissible in evidence, but only with the expenditure of substantial time in producing and examining various authenticating witnesses. The physician makes life-and-death decisions in reliance on them. His validation, expertly performed and subject to cross-examination, ought to suffice for judicial purposes.

FED. R. EVID. 703 advisory committee's note.

The expert testimony at issue in *Richardson* was a physician's opinion that the drug Bendectin caused the birth defects suffered by the plaintiffs' child. The expert, Dr. Alan K. Done, based his opinion on four types of evidence: (1) The chemical structure of Bendectin, (2) *in vitro* (test tube) studies, (3) *in vivo* (animal) studies, and (4) a reanalysis of the defendant's epidemiological studies showing no causal connection between the drug and the birth defects in question. *Richardson*, 857 F.2d at 826.

In his testimony, however, Dr. Done acknowledged that the chemical, *in vitro*, and *in vivo* studies alone could not form a sufficient basis to conclude that Bendectin caused birth defects. *Id.* And when confronted with epidemiological studies showing no statistically significant association between Bendectin and birth defects, Dr. Done conceded that he would not give an opinion as to causation unless epidemiological studies showed a statistically significant association between Bendectin and birth defects. *Id.* at 831. Furthermore, while Dr. Done found a statistically significant association, he did so only by recalculating the data in studies that found none, and his recalculations were never published or subjected to peer review. *Id.*

Richardson rejected Dr. Done's opinion, therefore, because it

lacked an adequate basis under Rule 703. The chemical, *in vitro*, and *in vivo* studies could not form a sufficient basis under Rule 703 because, as Dr. Done himself acknowledged, those studies were not of a type reasonably relied on by experts in the field to support a conclusion that Bendectin caused birth defects. *Id.* at 830. Because Dr. Done's recalculations of published epidemiological studies had never themselves been published or subject to peer review, we concluded that the recalculated epidemiological evidence also was insufficient to form an adequate scientific basis under Rule 703. *Id.* at 831.

In *Ealy v. Richardson-Merrell, Inc.*, 897 F.2d 1159 (D.C. Cir. 1990), we reaffirmed our holding in *Richardson*. That Bendectin case involved the same chemical, *in vitro*, *in vivo*, and reanalyzed epidemiological data that was offered in *Richardson*, along with an additional *in vivo* study. *Id.* Once again, we held that the expert opinions were inadmissible because they lacked an adequate scientific basis under Rule 703. *Id.* at 1162. In effect, we took judicial notice of *Richardson*'s conclusion that the chemical, *in vitro*, *in vivo*, and recalculated epidemiological studies were not of a type reasonably relied on by experts in the field. *Richardson*, we held, provided a "binding legal precedent governing the admissibility of expert opinion on the ability of Bendectin to cause human birth defects." *Id.* Because the experts in *Ealy* offered no different bases for their opinions, we held that the opinions were inadmissible under Rule 703. *Id.* at 1163.

Both *Ealy* and *Richardson* distinguished this court's earlier decision in *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984). The defendant in *Ferebee* argued that expert opinion that paraquat caused pulmonary fibrosis was inadmissible because it was too "novel." The defendant contended that, to be admissible, the expert opinion had to be generally accepted as reliable within the expert's field. Since there had never before been any evidence, nor any suggestion, that paraquat caused pulmonary fibrosis, the defendant argued that the evidence could not, at that point, be generally accepted in the scientific community. *Id.* at 1535.

The *Ferebee* court noted the difference between expert opinion based on controversial techniques or methods and expert opinion based on well-founded methods but which reaches a novel, and perhaps controversial, conclusion. *Id.* "As long as the basic methodology employed to reach such a conclusion is sound," the court held, "[the] law does not preclude recovery until a 'statistically significant' number of people have been injured or until science has the time and resources to complete sophisticated laboratory studies of the chemical." *Id.* at 1536.

Ferebee, therefore, did not involve a challenge to the underlying basis or methods of an expert's opinion under Rule 703, as did *Richardson* and *Ealy*. In fact, the experts in *Ferebee* relied on the "same diagnostic methodology" in forming their opinions. *Id.* at 1535. Rather, *Ferebee* involved a challenge to the novelty of the expert's ultimate conclusion. Because both experts relied on accepted methods and data but reached different conclusions based on that information, the court held that it was "a classic battle of the experts, a battle in which the jury must decide the victor." *Id.* As we recognized in *Richardson*, "if experts are willing to testify to causation in such situations *and their methodology is sound*, the jury verdict should not be disturbed." *Richardson*, 857 F.2d at 832 (emphasis added).

Four other Circuits have now reached conclusions similar to *Richardson* and *Ealy* in cases involving the drug Bendectin, although their reasoning has often differed. *See Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (6th Cir. 1992) (finding expert testimony insufficient to support a finding that Bendectin caused plaintiff's birth defects); *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 951 F.2d 1128 (9th Cir. 1991) (finding plaintiff's expert testimony inadmissible because reanalysis of peer-reviewed epidemiological studies is not a generally accepted scientific methodology); *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166, *reh'g denied*, 884 F.2d 167 (5th Cir. 1989) (finding expert testimony insufficient to establish causation); *Lynch v. Merrell-National Lab., Inc.*, 830 F.2d 1190 (1st Cir. 1987) (finding plaintiff's expert testimony to be inadmissible because it lacked

a proper foundation); *see also DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3rd Cir. 1990) (requiring the district court to assess the reliability of the methodology of plaintiff's expert).

In this case, the district court's reasons for granting summary judgment under *Richardson* are less than clear. At times it appears that the district court read *Richardson* as creating a heightened standard for causation in drug liability cases such as this one. The district court held that *Richardson* requires plaintiffs to bring forward "specific, admissible scientific proof in support of their claim that a drug is responsible for causing plaintiff's birth defects." *Memorandum Opinion*, at 8. The court later noted as part of the basis for its grant of summary judgment that the affidavits submitted by the Ambrosinis' experts failed to set forth the facts and data underlying their opinions. *Id.* at 10. In other places, however, the district court seems to have assumed that the basis for the experts' opinions was the same as in *Richardson*, and rejected the opinions on that ground without mentioning Rule 703. *Id.* In any event, we think that the district court's holding reflects a misunderstanding of *Richardson*.

The *Richardson* court did not address the specificity with which an expert must state the basis for his opinion in an affidavit in response to a motion for summary judgment. *Richardson* held only that the chemical, *in vitro*, and *in vivo* studies relied on by the plaintiff's expert could not form an adequate basis for the conclusion that Bendectin caused the plaintiff's birth defects because the expert himself conceded that those studies alone would not reasonably be relied on by experts in the field. *Richardson*, 857 F.2d at 830. Furthermore, because the expert's reanalyzed epidemiological data had never been published or subject to peer review, the opinion based on that reanalysis was inadmissible in the face of a wealth of published epidemiological studies that concluded to the contrary. *Id.* at 831. Nowhere in either *Richardson* or *Ealy* did we state that an expert's opinion (or an expert's affidavit in response to a motion for summary judgment) must specify the basis for the opinion to be admissible under Rule 703.

Indeed, such a holding would be contrary to Rule 705. That Rule provides:

> The expert may testify in terms of opinion or inference and give reasons therefor without prior disclosure of the underlying facts or data, unless the court requires otherwise. The expert may in any event be required to disclose the underlying facts or data on cross-examination.

FED. R. EVID. 705. Rule 705 eliminates the prior practice of requiring an expert to set out, specifically, the facts and data underlying an opinion before allowing the expert to testify. *See* JACK B. WEINSTEIN & MARGARET A. BERGER, WEINSTEIN'S EVIDENCE ¶ 705[01], at 5-6 (1991). Under Rule 705, an expert's affidavit, no matter what the basis, cannot be excluded solely because it fails to disclose the facts or data underlying the opinion.

The Ambrosinis responded to Upjohn's motion for summary judgment by offering the affidavits of two experts: Dr. Strom, who concluded that progestins, in general, cause birth defects, and Dr. Goldman who concluded, more specifically, that Depo-Provera caused Teresa Ambrosini's birth defects. At that point, pursuant to Rule 705, the court could have required Dr. Strom and Dr. Goldman to disclose the bases for their opinions so that it could determine whether the opinions had an adequate foundation (i.e. whether they were based on information that experts in the field would reasonably rely on in determining whether a particular drug causes birth defects). Only then could the court determine whether the affidavits were admissible under Rule 703. A court must know the basis for an expert's opinion before it can determine that the basis is not of a type reasonably relied on by experts in the field. *See e.g. In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829, 854-55 (3d Cir. 1990). Because the court below never delved further into the basis for the expert opinions, particularly the one supplied by Doctor Goldman, *see infra* pp. 13-14, we are persuaded that the court acted prematurely in granting summary judgment on the basis of *Richardson*.

Upjohn would have us read the *Richardson* decision more

broadly, arguing that *Richardson* did more than rule on the admissibility of expert opinion under Rule 703. Upjohn contends that *Richardson* upheld the district court's decision to issue a j.n.o.v. because expert conclusions based on chemical, *in vitro*, *in vivo*, and unpublished recalculations of epidemiological data do not provide "sufficient evidence upon which a jury could properly base a verdict for the plaintiff." But *Richardson* did not hold that chemical, *in vitro*, and *in vivo* studies would be insufficient, in all cases, to support a conclusion that a particular drug causes birth defects. *Richardson* held only that Dr. Done's testimony was inadmissible under Rule 703 because he acknowledged that the data underlying his opinion was not of a type reasonably relied on by experts in the field. And because the court found that, without that evidence, no reasonable jury could find for the plaintiff, it upheld the district court's decision to grant a j.n.o.v.. *See Richardson*, 857 F.2d at 833.

The distinction we draw between this case and *Richardson* is not a minor one. When a court denies the right to have a jury decide a disputed issue, especially one of a scientific nature, its reasons for doing so must be strong. *See Ferebee*, 736 F.2d at 1535 (expert opinion based on sound scientific methodology presents "a classic battle of the experts, a battle in which the jury must decide the victor"). Science is a rapidly changing field. Methodologies rejected today may be universally accepted in the future. DNA evidence as a method of identification, for example, was virtually unheard of 25 years ago but is gaining widespread acceptance in the courts today. *See* Comment, *Trial By Certainty: Implications of Genetic "DNA Fingerprints"*, 39 EMORY L. J. 309 (1990) (citing *State v. Andrews*, 533 So.2d 841 (Fla. Dist. Ct. App. 1988) as the first case in the United States accepting DNA evidence). Our decisions must leave the way open for these changes.

Upjohn makes much of the fact that the record in this case is the same as the record that this court considered when it affirmed the district court's decision to grant summary judgment to Merrell-Dow, Upjohn's former co-defendant in this case. We point out, however, that the district court granted Merrell-Dow's

motion for summary judgment only after issuing an Order to Show Cause requiring plaintiffs to identify a basis, admissible under Rule 703 and *Richardson*, for their expert's opinion that Bendectin caused Teresa's birth defects. *See Koller v. Richardson-Merrell, Inc.*, No. 80-1258, slip op. at 2 (D.D.C. June 30, 1989), *amended sub nom. Ambrosini v. Richardson-Merrell, Inc.*, No. 86-0278 (D.D.C. July 12, 1989), *aff'd*, No. 90-7148 (D.C. Cir. 1990). Only after the Ambrosinis failed to identify a basis for their expert's opinion *other than* the chemical, *in vitro*, *in vivo*, and reanalyzed epidemiological data rejected in *Richardson* did the court grant Merrell-Dow's motion for summary judgment. *Id.* at 8. This is precisely the sort of inquiry the court must undertake before determining whether expert testimony has an adequate foundation under Rule 703. No show cause order was issued in this case before the district court granted Upjohn's motion.

B. The Standards for Summary Judgment Under Rule 56.

Our inquiry does not end with the determination that the district court erred in granting summary judgment on the basis of this court's decision in *Richardson*, for even if the expert affidavits were admissible under Rule 703, summary judgment would have been proper if the affidavits were not sufficient to create a genuine issue of material fact. This court, as well as others, has recognized that the issue of admissibility of an expert's opinion under Rules 703 and 705 is separate and distinct from the issue whether the testimony is sufficient to withstand a motion for summary judgment under Rule 56. *See Merit Motors, Inc. v. Chrysler Corp.*, 569 F.2d 666, 673 (D.C. Cir. 1977); *Monks v. General Elec. Corp.*, 919 F.2d 1189, 1192-93 (6th Cir. 1990); *Mid-State Fertilizer Co. v. Exchange Nat'l Bank of Chicago*, 877 F.2d 1333, 1339 (7th Cir. 1989); *Evers v. General Motors Corp.*, 770 F.2d 984, 986 (11th Cir. 1985); *United States v. Various Slot Machines on Guam*, 658 F.2d 697, 700-701 (9th Cir. 1981).

Rule 56(e) of the Federal Rules of Civil Procedure states that, in order to defeat a well-supported motion for summary judg-

ment, an affidavit in response to the motion "must set forth *specific facts* showing that there is a genuine issue for trial." FED. R. CIV. P. 56(e) (emphasis added). Upjohn insists, and the district court apparently would agree, that because the affidavits of Doctors Strom and Goldman do not set forth the "specific facts" or reasoning behind their opinions, they are insufficient, under Rule 56(e), to defeat the motion for summary judgment. *See Memorandum Opinion*, at 12.

In support of its contention, Upjohn cites to a number of cases, including this court's decision in *Merit Motors*. But in *Merit Motors* we did not uphold the district court's grant of summary judgment because the expert failed to identify the basis for his opinion. Rather, we upheld summary judgment because the district court correctly determined that the plaintiff's expert was unfamiliar with the record in the case and because the expert's opinion was based on speculations and hypotheses that were contradicted by his own deposition testimony. *See Merit Motors*, 569 F.2d at 672; *see also Monks v. General Elec. Co.*, 919 F.2d at 1192 (standard articulated in *Merit Motors* is that affidavits by experts who are unfamiliar with the record are insufficient to withstand summary judgment). The other cases that Upjohn cites are similarly distinguishable.

Dr. Goldman's affidavit stated a specific fact, namely that, based on "the available scientific and epidemiological data concerning progestin and progesterone agents including the product manufactured by the defendant Upjohn Company known as Depo-Provera," as well as a review of relevant medical records of Mrs. Ambrosini and her daughter Teresa, Depo-Provera caused Teresa Ambrosini's birth defects. We are convinced that, if admissible, Dr. Goldman's affidavit gave a sufficient factual basis to defeat summary judgment at this point. We need not decide the more difficult question whether Rule 56 would be satisfied by the bare conclusion that Depo-Provera caused Teresa's birth defects. *See Bulthuis v. Rexall Corp.*, 789 F.2d 1315 (9th Cir. 1985) (distinguishing between an affidavit that fails to state any basis for its opinion and an affidavit that discloses the general basis for its opinion but fails to explain, in

detail, how the opinion was reached). Nor need we decide whether Dr. Strom's affidavit, which concluded only that progestins cause birth defects in general, could defeat summary judgment even at the outset in this case.

CONCLUSION

Without a further inquiry into the factual basis for the opinion of Doctors Goldman and Strom, the district court erred in granting summary judgment based on this court's decision in *Richardson*. And because Dr. Goldman's affidavit set forth a specific fact, we are persuaded that, if admissible, it was enough to defeat Upjohn's motion for summary judgment. We reverse the district court's order granting summary judgment in favor of Upjohn, therefore, and remand for further proceedings consistent with this opinion. Because the district court based its grant of summary judgment in favor of Dr. Labarraque on the same grounds, we also reverse the grant of summary judgment with respect to Dr. Labarraque. On remand, it will remain open to the district court to address the defendants' opposition to the plaintiffs' untimely substitution of Doctors Strom and Goldman in their Rule 26(b)(4) list.

Reversed and remanded.

APPENDIX E

MICHIGAN SUPREME COURT

LAWRENCE R. DePYPER, SR., Individually;
and JANE N. DePYPER, Individually, and as
Next Friend of LAWRENCE R. DePYPER, JR.,
Plaintiffs-Appellees,

v.

PAUL F. NAVARRO, D.O.;
PAUL F. NAVARRO, D.O., P.C.,
Defendants,

and

MERRELL DOW PHARMACEUTICALS, INC.,
Subsidiary of DOW CHEMICAL COMPANY;
MERRELL NATIONAL LABORATORIES, INC.,
Defendants-Appellants.

SC: 92174, 92409
COA: 116390
LC: 83 303467 NM

Entered: April 21, 1992

ORDER

On order of the Court, the application for leave to appeal and the delayed application for leave to appeal are considered, and they are DENIED, because we are not persuaded that the questions presented should now be reviewed by this Court.

Riley, J., would grant leave to appeal.

STATE OF MICHIGAN
COURT OF APPEALS

LAWRENCE R. DePYPER, SR., Individually; and JANE N. DePYPER, Individually, and as Next Friend of LAWRENCE R. DePYPER, JR.,
Plaintiffs-Appellants,

v.

PAUL F. NAVARRO, D.O.; PAUL F. NAVARRO, D.O., P.C., MERRELL DOW PHARMACEUTICALS, INC., Subsidiary of DOW CHEMICAL COMPANY; MERRELL NATIONAL LABORATORIES, INC.,
Defendants-Appellants.

No. 116380

May 9, 1991

Before: Holbrook, Jr., P.J., and Wahls and T.G. Kavanagh, JJ.

PER CURIAM.

Plaintiffs' suit alleging that the limb reduction birth defects suffered by plaintiff minor, Lawrence R. DePyper, Jr., were caused by the ingestion of Bendectin, a prescription drug developed and marketed by defendant, Merrell-Dow Pharmaceuticals, Inc., and its predecessors, was dismissed on defendants' motion for summary disposition.

The trial court granted the motion on two bases: 1) on its conclusion that plaintiffs could not produce at trial admissible or sufficient evidence that Bendectin is a teratogen capable of causing the type of birth defects present here and also 2) that even if such proof could be produced, the mother's pregnancy here had progressed too far for the ingestion of Bendectin to have been a proximate cause of the injuries. We reverse.

1. *Admissibility of the Proffered Expert Testimony*

The trial court based her conclusion on the admissibility of the proffered expert opinion on the authority and reasoning of the court in *Lynch v. Merrell-National Laboratories*, 830 F.2d 1190 (CA 1, 1987), and *Richardson v. Richardson-Merrell, Inc.*, 649 F.Supp 799 (DDC, 1986), *aff'd* 827 F.2d 823 (CADC, 1988), *cert den* ___ US ___; 110 S.Ct 218; 107 L.Ed.2d 171 (1989).

We are satisfied that the evidentiary rule of those cases does not comport with Michigan jurisprudence.

Michigan still follows the so-called *Davis/Frye* rule which requires that to be admissible expert testimony concerning a novel form or application of scientific evidence must be shown to have general scientific acceptance among impartial and disinterested experts in the field.

In this case the field is teratology. The *Davis/Frye* inquiry must then be: "Do impartial and disinterested experts in the field of teratology generally accept the methodology employed by plaintiffs' expert in assessing the impact of *in vivo*, *in vitro*, chemical structure and animal studies in determining teratogenicity?

If so, the expert's opinion is admissible -- otherwise it is not.

Here the trial court said,

> Unable to prove directly how Bendectin harmed plaintiff minor, plaintiffs unavoidably rely on circumstantial evidence to establish the requisite causal link. Through the testimony of experts in a variety of disciplines, including pharmacology, embryology, veterinary medicine, and pediatrics, plaintiffs primarily (i) seek to prove that Bendectin is capable of causing limb reduction defects by comparing Bendectin to other known teratogenic agents on the basis of analogous chemical structure, and (ii) introducing the results of *in vitro* and *in vivo* animal studies. Cross-examination of these experts

> invariably elicited testimony that (i) chemical resemblance does not necessarily mean similar chemical activity, and (ii) differences in genetic make-up and metabolic rate, together with the inordinately large dosages typically administered, cast doubt on the scientific validity of animal studies when used to predict human physiological response. Because this evidence is identical to that described and rejected in *Lynch*, and *Richardson*, as capable of proving causation, singularly or collectively, *Lynch*, 830 F.2d at 1194 (citations omitted), further discussion is unwarranted.

In our view, without the *Davis/Frye* inquiry suggested above (which was not made here -- nor in *Lynch* and *Richardson*, *supra*) the court's ruling is premature.

2. *Time of Ingestion and Probable Cause*

Both the dates of conception and the ingestion of Bendectin are matters of fact about which there is conflicting evidence and which should be determined by the jury.

Accordingly the decision of the trial court is reversed and the case remanded for further proceedings consonant herewith.

/s/Donald E. Holbrook, Jr.
/s/Myron H. Wahle
/s/Thomas Giles Kavanagh

APPENDIX F

IN THE DISTRICT COURT OF
NUECES COUNTY, TEXAS
214TH JUDICIAL COURT

EARNEST HAVNER & MARILYN HAVNER
ON BEHALF OF THEIR MINOR CHILD KELLY HAVNER

VS.

MERRELL DOW PHARMACEUTICALS, INC.

CAUSE NO. 88-3915-F

FINAL JUDGMENT

ON THE 3rd day of September, 1991, came on to be heard the above-entitled and numbered cause and Ernest and Marilyn Havner as Representatives and Next Friend of Kelly Havner, the Plaintiffs, appeared in person and by attorney of record, and announced ready for trial, and Merrell-Dow Pharmaceuticals, Inc., the Defendant, appeared in person and by attorney of record and announced ready for trial, and the jury having been previously demanded, a jury consisting of twelve (12) good and lawful jurors was duly impaneled and the case proceeded to trial.

At the conclusion of the evidence, the Court submitted the case to the jury on questions and instructions. The Charge of the Court, including the questions submitted to the jury, and the verdicts of the jury, are incorporated herein for all purposes by reference. After the jury returned their verdicts, Plaintiffs moved the Court to enter a judgment reflecting the full amount of the jury verdicts, actual damages of Three Million Seven Hundred Fifty Thousand Dollars ($3,750,000.00), prejudgment interest at ten percent (10%) simple interest on said amount from the date of the filing of the Original Petition in this matter, July 15, 1988, until the day preceding entry of judgment and punitive damages in the amount of Thirty Million Dollars ($30,000,000),

and moved the Court to rule that Section 41.007 of the Texas Rules of Civil Practice & Remedies Code is unconstitutional or alternatively, Defendant Merrell-Dow waived said limitation of that statute on the amount of punitive damages by failing to properly and specifically plead it, or, alternatively, moved for entry of judgment on the verdict to include prejudgment interest on the actual damages of Three Million Seven Hundred Fifty Thousand Dollars ($3,750,000.00) to run from the date of the filing of the Original Petition until the day preceding entry of judgment and for punitive damages in the amount of four (4) times the actual damages, said sum being Fifteen Million Dollars ($15,000,000.00). Defendant, Merrell-Dow moved the Court to render Judgment Non Obstante Veredicto reflecting a judgment that Plaintiffs take nothing as to their claims.

The Court, having considered the motions of Plaintiffs and Defendant, and it appearing to the Court that the verdicts of the jury were for the Plaintiffs and against Defendant, Merrell-Dow, that there is evidence of probative force to sustain the verdicts of the jury, and that an instructed verdict in favor of the Defendant would not have been proper regarding the questions submitted to the jury, judgment should be rendered on the verdicts in favor of the Plaintiffs and against the Defendant. IT IS THEREFORE

ORDERED, ADJUDGED and DECREED by the Court that Plaintiffs' Motion for Entry of Judgment reflecting actual damages of Three Million Seven Hundred Fifty Thousand and no/100 Dollars ($3,750,000.00), prejudgment interest on actual damages from July 15, 1988 until the day preceding the entry of this judgment and exemplary damages in the amount of four time the actual damages, said sum being Fifteen Million Dollars ($15,000,000), is granted. IT IS FURTHER

ORDERED, ADJUDGED and DECREED that Plaintiffs' motion to determine the Section 41.007 of the Texas Civil Practice and Remedies Code is unconstitutional is denied. IT IS FURTHER

ORDERED, ADJUDGED and DECREED that Plaintiffs' Motion to enter judgment for the full amount of exemplary

damages because Plaintiffs' claim Merrell-Dow has waived the damage limitation of Texas Civil Practice and Remedies Code Section 41.007 is denied. IT IS FURTHER

ORDERED, ADJUDGED and DECREED that Defendant Merrell-Dow's Motion for Judgment Non Obstante Veredicto is denied. IT IS FURTHER

ORDERED, ADJUDGED and DECREED by the Court that Plaintiffs, Ernest and Marilyn Havner, as Next Friends for Kelly Havner, have and recover from Defendant, Merrell-Dow the sum of Twenty Million Two Hundred Five Thousand Eight Hundred Twenty-One and 80/100 Dollars ($20,205,821.80). IT IS FURTHER

ORDERED, ADJUDGED and DECREED that the judgment hereby rendered shall bear interest at the rate of ten percent (10%) simply interest from the date of judgment until paid.

All costs of Court expended or incurred in this cause are hereby adjudged against Defendant, Merrell-Dow. All writs and processes for the enforcement and collection of this judgment or costs may issue as necessary. All other relief not expressly granted herein is denied.

SIGNED on this 1st day of June, 1992.

Mike Westergren
District Judge Presiding